

EXHIBIT A

Designation Run Report

Civarella 11-12-13 Booker Depo Designations Final2

Ciavarella, David 11-12-2013

Plaintiffs Designations 00:20:49

Defense Designations 00:08:35

P & D Affirmatives 00:09:54

Total Time 00:39:18



03_12_18 Combo final2-Civarella 11-12-13 Booker Depo Designations Final2

Page/Line	Source	ID
11:9 - 11:11	Ciavarella, David 11-12-2013 (00:00:04) 11:9 Q. Good morning. Would you please state 11:10 your full name? 11:11 A. Yeah, David Ciavarella.	03_12_18 Combo final2.1
19:23 - 20:2	Ciavarella, David 11-12-2013 (00:00:20) 19:23 from 2004 to, what was it, 2007 or 19:24 2008, there was a period of transition. I was 19:25 in -- had corporate clinical affairs in charge 20:1 of the human clinical trials. And then there 20:2 was also another component	03_12_18 Combo final2.2
20:7 - 20:14	Ciavarella, David 11-12-2013 (00:00:40) 20:7 The medical affairs component of that 20:8 was an assortment of things related to product 20:9 design working with the quality assurance group 20:10 when there were product complaints, review of 20:11 product labeling, all of the labeling, and also 20:12 some consultation with the law department when 20:13 either patients or their attorneys submitted 20:14 claims for injury of some sort.	03_12_18 Combo final2.3
34:13 - 34:15	Ciavarella, David 11-12-2013 (00:00:06) 34:13 Q. Have you ever written an article that 34:14 involves IVC filters? 34:15 A. No.	03_12_18 Combo final2.4
36:9 - 36:19	Ciavarella, David 11-12-2013 (00:00:27) 36:9 Q. Have you ever considered doing a 36:10 retrospective analysis or study to submit to a 36:11 peer-reviewed article as they relate to any of 36:12 the Bard IVC filters? 36:13 A. No. 36:14 Q. Have you ever considered looking at 36:15 any of the adverse events and the details of the 36:16 adverse events and submitting it -- one or more 36:17 of those to publication as a case report or a 36:18 case series? 36:19 A. No.	03_12_18 Combo final2.5
36:20 - 37:3	Ciavarella, David 11-12-2013 (00:00:26) 36:20 Q. Why wouldn't you want to do something 36:21 like that? 36:22 A. Well, two main reasons. One is it's 36:23 not my expertise. The people who utilize, treat	03_12_18 Combo final2.6

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36:24 patients every day are the experts. My role is
36:25 no longer direct patient care.

37:1 Q. Right.

37:2 A. And, you know, secondly, it's a matter

37:3 of priority. I have other things to do.

43:15 - 43:20

Ciavarella, David 11-12-2013 (00:00:16)

03_12_18 Combo final2.7

43:15 Q. And when was the last time before 2003
43:16 that you had actually had an interaction with a
43:17 patient where you were getting their informed
43:18 consent or recommending various types of
43:19 alternative therapeutic, you know, remedies?
43:20 A. 1995.

45:7 - 45:13

Ciavarella, David 11-12-2013 (00:00:17)

03_12_18 Combo final2.8

45:7 Q. Well, what's a health hazard
45:8 evaluation?

45:9 A. Well, it's a document -- it's a
45:10 document written to provide a health care
45:11 professional evaluation of a complaint or a
45:12 hazard reported to a company concerning one of
45:13 its products.

48:25 - 49:8

Ciavarella, David 11-12-2013 (00:00:39)

03_12_18 Combo final2.9

48:25 Q. Now, these health hazard evaluations
49:1 that you agreed with the definition that I gave
49:2 you, they involve also whoever was doing these,
49:3 that person making decisions about whether or
49:4 not, you know, there was a likelihood of a
49:5 recurrence of the problem; right? They made
49:6 those calls?

49:7 A. They didn't make those calls. We
49:8 provided our assessment.

61:13 - 61:17

Ciavarella, David 11-12-2013 (00:00:13)

03_12_18 Combo final2.10

61:13 Q. And that's why we -- some doctors
61:14 think that these filters should be put in place
61:15 to prevent that sort of event from happening in
61:16 patients who are at risk of that happening?
61:17 A. Yes.

61:18 - 61:24

Ciavarella, David 11-12-2013 (00:00:19)

03_12_18 Combo final2.11

61:18 Q. And that -- when we talk about the
61:19 benefit of an IVC filter and risk analysis,
61:20 we're talking about the benefit of that filter

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61:21 staying where it was put and stopping a clot
 61:22 from reaching either the heart or the lungs;
 61:23 right?
 61:24 A. Yes.

75:14 - 75:17

Ciavarella, David 11-12-2013 (00:00:21)

03_12_18 Combo final2.12

75:14 MR. LOPEZ: No. 21 is regulatory

CIAVARELLA21.1.2

75:15 affairs manual, Bard, with Bates Nos.

CIAVARELLA21.1.4

75:16 BPV-17-01-00024667, through and including

75:17 684.

75:21 - 76:13

Ciavarella, David 11-12-2013 (00:01:01)

03_12_18 Combo final2.13

75:21 Q. Was this a document that was part of

clear

75:22 your -- you know, material that was provided to

75:23 you when you started at Bard or at least shortly

75:24 thereafter?

75:25 A. Well, the "Title: Product Remedial

76:1 Actions" certainly is. I would -- the date here

76:2 is October of 2000. So if that were the version

76:3 that were officially in play or officially being

76:4 used at the time that I was hired, then, yes,

76:5 unless there was an updated version.

76:6 Q. Okay. And this was the manual that --

76:7 at least internally at Bard that they imposed

76:8 upon themselves to dictate whether a product

76:9 should be recalled or whatever type of safety

76:10 action should be taken with respect to their

76:11 products; correct?

76:12 A. Yeah, well, it's a document describing

76:13 how they should go about remedial action plans.

77:2 - 77:9

Ciavarella, David 11-12-2013 (00:00:38)

03_12_18 Combo final2.14

77:2 Q. And would you agree with me that if a

77:3 product had an unacceptable risk, that it's a

77:4 product that probably should be recalled?

77:5 A. If a product has an unacceptable risk

77:6 that can't be mitigated in any way or if the

77:7 benefit to patients is outweighed by the risk,

77:8 then I imagine that a company would decide to no

77:9 longer sell that product.

80:4 - 80:13

Ciavarella, David 11-12-2013 (00:00:32)

03_12_18 Combo final2.15

80:4 Q. And, by the way, the company shouldn't

80:5 make these decisions based in any way on a

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80:6 potential adverse effect on market share or
 80:7 profitability or income; right? That would be
 80:8 wrong?
 80:9 A. The decision to recall a product
 80:10 should be based upon the safety profile, the
 80:11 risk/benefit analysis of that product and its
 80:12 effect on patients and on, you know, the users
 80:13 of the product.

84:22 - 85:3

Ciavarella, David 11-12-2013 (00:00:15)

03_12_18 Combo final2.16

84:22 Q. The company shouldn't
 84:23 determine whether or not this type of severity
 84:24 and this type of adverse reaction and this
 84:25 frequency is at a level that all doctors should
 85:1 accept, doctors have -- all doctors and patients
 85:2 have a right to make that decision on their
 85:3 own --

86:7 - 86:16

Ciavarella, David 11-12-2013 (00:00:42)

03_12_18 Combo final2.17

86:7 THE WITNESS: Yeah, I don't know
 86:8 how to answer that question. Whenever a
 86:9 company makes a product, develops a product
 86:10 for use, it makes an assessment of the
 86:11 frequency with which it might fail or be
 86:12 associated with an adverse outcome. And
 86:13 when those numbers are low enough, I don't
 86:14 know what would be gained by trying to
 86:15 describe in every circumstance that much
 86:16 detail.

94:3 - 94:7

Ciavarella, David 11-12-2013 (00:00:14)

03_12_18 Combo final2.18

94:3 Q. Okay. I understand. And if the
 94:4 doctor has a certain expectation about a device,
 94:5 it's important for him to have that information
 94:6 as to whether or not this device is going to
 94:7 meet his expectations; right?

94:9 - 94:9

Ciavarella, David 11-12-2013 (00:00:00)

03_12_18 Combo final2.19

94:9 THE WITNESS: Yes.

104:16 - 104:18

Ciavarella, David 11-12-2013 (00:00:10)

03_12_18 Combo final2.20

104:16 Q. What is MAUDE?

104:17 A. That's the FDA's database for medical
 104:18 device reporting.

106:9 - 106:23

Ciavarella, David 11-12-2013 (00:00:42)

03_12_18 Combo final2.21

Page/Line	Source	ID
	106:9 Q. I'm just trying to find out 106:10 from you what your position and Bard's position 106:11 is about the significance of what is being 106:12 reported and trended via the MAUDE database. 106:13 A. Well -- 106:14 Q. Can you tell me what that is? 106:15 A. -- with respect to our own reports 106:16 that we provide to the MAUDE database, we 106:17 already know that information. So whether that 106:18 information goes to the MAUDE database or not, 106:19 Bard has access to that information and can use 106:20 it to assure the quality of its product. 106:21 With respect to our competitors' 106:22 information, it's a very imperfect and, 106:23 therefore, unreliable database.	
110:21 - 111:3	Ciavarella, David 11-12-2013 (00:00:23) 110:21 Q. Again, looking at Exhibit 110:22 21, this is the -- at least the internal 110:23 document that should have guided Bard in its 110:24 assessment and evaluation and determination as 110:25 to whether or not the Recovery or any version of 111:1 the G2 should have been recalled from the 111:2 market; is that right? 111:3 A. Yes.	03_12_18 Combo final2.22
131:6 - 131:12	Ciavarella, David 11-12-2013 (00:00:15) 131:6 Q. But there's a general consensus 131:7 that that might be, in fact, the case, you're 131:8 only getting 1 to 5 percent of what's actually 131:9 happening, actually reported to the company or 131:10 FDA? 131:11 A. I mean, maybe yes, maybe no. That's 131:12 the problem with it is you don't know.	03_12_18 Combo final2.23
131:16 - 131:23	Ciavarella, David 11-12-2013 (00:00:19) 131:16 Q. But there was at one point in 131:17 time -- I can show you the document later -- 131:18 where you, Dr. Ciavarella, said one of the 131:19 problems with reporting of events, voluntary 131:20 reporting, is there's a consensus that you might 131:21 be only getting 1 to 5 percent of the actual 131:22 events; right?	03_12_18 Combo final2.24

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174:22 - 175:9	<p>131:23 A. Could be. Yeah, there's a consensus.</p> <p>Ciavarella, David 11-12-2013 (00:00:50)</p> <p>174:22 Q. let's look at the caval</p> <p>174:23 perforation issue that we talked about earlier</p> <p>174:24 as it relates to the G2. If you look at the</p> <p>174:25 rates -- by the way, that does say "Rates,"</p> <p>175:1 doesn't it, in the column? They use the word</p> <p>175:2 "Rates"?</p> <p>175:3 A. Down at the bottom they do, yeah.</p> <p>175:4 Q. Okay. And according to this data, the</p> <p>175:5 rates of caval perforations compared to the SNF</p> <p>175:6 and the G2, is the G2 is still, at least</p> <p>175:7 according to this data, about -- what's that,</p> <p>175:8 about 800 percent greater?</p> <p>175:9 A. No.</p>	03_12_18 Combo final2.25
175:10 - 175:12	<p>Ciavarella, David 11-12-2013 (00:00:02)</p> <p>175:10 Q. I'm just asking you to do some math</p> <p>175:11 with me.</p> <p>175:12 A. You're misinterpreting the data.</p>	03_12_18 Combo final2.26
176:2 - 176:8	<p>Ciavarella, David 11-12-2013 (00:00:14)</p> <p>176:2 Q. If you</p> <p>176:3 look at the difference between the rates that</p> <p>176:4 are reported on this document, the rates of</p> <p>176:5 caval perforations are greater for the G2 when</p> <p>176:6 compared to both the Recovery and the Simon</p> <p>176:7 Nitinol filter?</p> <p>176:8 A. Yes.</p>	03_12_18 Combo final2.27
179:16 - 179:25	<p>Ciavarella, David 11-12-2013 (00:00:32)</p> <p>179:16 Q. Well, eventually didn't Dr. Lehmann</p> <p>179:17 take some of this data -- I don't know what time</p> <p>179:18 period it was -- the MAUDE data, and determine</p> <p>179:19 that there was a statistically significant</p> <p>179:20 increased risk of migration, perforation,</p> <p>179:21 fractures, and other complications involved with</p> <p>179:22 the Recovery filter when compared to all other</p> <p>179:23 filters on the market by a factor of somewhere</p> <p>179:24 between the low 4s and the mid 5s?</p> <p>179:25 A. Yeah.</p>	03_12_18 Combo final2.28
180:2 - 180:9	<p>Ciavarella, David 11-12-2013 (00:00:28)</p> <p>180:2 A. He did an analysis based on reported</p>	03_12_18 Combo final2.29

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	180:3 rates from MAUDE and made some statistical 180:4 comparisons which he said were really not valid. 180:5 Q. Well, he said they were statistically 180:6 significant. 180:7 A. Well, the statistical test was done, 180:8 but the use of those data are not appropriate 180:9 for comparison rates.	
180:15 - 180:21	Ciavarella, David 11-12-2013 (00:00:20) 180:15 Q. -- he said that these increased risks 180:16 of somewhere between 400 percent and 500 percent 180:17 were statistically significant when compared to 180:18 all other filters on the market; right? 180:19 A. I don't remember the exact numbers, 180:20 but, yes, he did make some statements about 180:21 statistically significant differences.	03_12_18 Combo final2.30
182:24 - 182:25	Ciavarella, David 11-12-2013 (00:00:06) 182:24 Exhibit 28 is 182:25 a PowerPoint.	03_12_18 Combo final2.31 CIAVARELLA28.1.1
183:4 - 183:5	Ciavarella, David 11-12-2013 (00:00:07) 183:4 And it's a filters 183:5 complaint history data as of 7/31/07.	03_12_18 Combo final2.32 CIAVARELLA28.1.5
184:21 - 184:24	Ciavarella, David 11-12-2013 (00:00:11) 184:21 aren't we talking about frequency 184:22 when you look at rates? 184:23 A. Yes, frequency. Rate is just a way 184:24 to -- one way to describe a frequency.	03_12_18 Combo final2.33 clear
184:25 - 185:11	Ciavarella, David 11-12-2013 (00:00:33) 184:25 Q. Did you have any better data, by the 185:1 way, that would give us rates or frequency in 185:2 comparing Recovery or G2 to competitive products 185:3 or the Recovery in G2 to the Simon Nitinol 185:4 filter? 185:5 A. Well, I think the only other way to 185:6 make comparisons, and it's very difficult to do 185:7 so, would be by analysis of published literature 185:8 in journal articles, so if you had an article 185:9 published about an adverse event profile of one 185:10 of our competitors versus papers that had been 185:11 published on our filter.	03_12_18 Combo final2.34
205:25 - 206:8	Ciavarella, David 11-12-2013 (00:00:27)	03_12_18 Combo final2.35

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	<p>205:25 Q. We've been talking about, you know,</p> <p>206:1 migration and embolization of the entire filter,</p> <p>206:2 but you've learned that you can have</p> <p>206:3 embolization of just a fragment of an IVC filter</p> <p>206:4 that can migrate to the heart and cause a</p> <p>206:5 fatality; true?</p> <p>206:6 A. Yes, true. I just don't remember if</p> <p>206:7 it caused a fatality. I know it caused some</p> <p>206:8 serious adverse events.</p>	
206:16 - 207:11	<p>Ciavarella, David 11-12-2013 (00:01:10)</p> <p>206:16 What are some of the</p> <p>206:17 risks associated with such an event?</p> <p>206:18 A. Well, if a -- if the piece of metal</p> <p>206:19 moves up into the heart, the danger is that it</p> <p>206:20 could potentially pierce some critical structure</p> <p>206:21 in the heart, either a heart valve or the heart</p> <p>206:22 muscle itself, cause an arrhythmia, cause</p> <p>206:23 bleeding around the heart.</p> <p>206:24 Q. I think you wrote in one of your HHEs</p> <p>206:25 that it could even cause a stroke, you can have</p> <p>207:1 a stroke from a fragment?</p> <p>207:2 A. If the fragment moved from the right</p> <p>207:3 atrium to the left atrium and then entered the</p> <p>207:4 circulation on the left side, you could have a</p> <p>207:5 stroke, yes.</p> <p>207:6 Q. So that's a risk -- that's a</p> <p>207:7 catastrophic risk associated with a fracture</p> <p>207:8 fragment from an IVC filter?</p> <p>207:9 A. That's a -- those are theoretical</p> <p>207:10 risks and I believe, as I remember fairly well,</p> <p>207:11 that some of those happened.</p>	03_12_18 Combo final2.36
247:15 - 247:20	<p>Ciavarella, David 11-12-2013 (00:00:20)</p> <p>247:15 Q. Well, let me ask you, how many of the</p> <p>247:16 five people between December 2004 and June of</p> <p>247:17 2005 who had these migrations were aware of the</p> <p>247:18 ten that happened before?</p> <p>247:19 A. I don't know.</p>	03_12_18 Combo final2.37
247:22 - 247:23	<p>247:20 Q. Probably none of them; right?</p> <p>Ciavarella, David 11-12-2013 (00:00:01)</p> <p>247:22 THE WITNESS: Potentially none of</p>	03_12_18 Combo final2.38

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250:2 - 250:5	247:23 them. Ciavarella, David 11-12-2013 (00:00:10)	03_12_18 Combo final2.39
250:7 - 250:7	250:2 Q. Would it be reasonable for a doctor 250:3 who's considering using a Recovery filter in 250:4 2005 to want to know whether or not that device 250:5 had a higher failure rate than other devices? Ciavarella, David 11-12-2013 (00:00:00)	03_12_18 Combo final2.40
250:9 - 250:12	250:7 THE WITNESS: Yes. Ciavarella, David 11-12-2013 (00:00:09)	03_12_18 Combo final2.41
250:14 - 250:15	250:9 Q. Would you also agree that he couldn't 250:10 do a proper analysis without knowing all of the 250:11 risks, not only the type of risk but the 250:12 frequency of risk? Ciavarella, David 11-12-2013 (00:00:03)	03_12_18 Combo final2.42
265:18 - 265:21	250:14 THE WITNESS: Well, if he -- 250:15 sure, if he didn't have the information. Ciavarella, David 11-12-2013 (00:00:30)	03_12_18 Combo final2.43
267:16 - 267:23	265:18 Q. No. 33 is a December 27, 2005, 265:19 document, which is an e-mail string that starts 265:20 with a December 20, 2005, e-mail from a Cindi 265:21 Walcott to you, Dr. Ciavarella. Ciavarella, David 11-12-2013 (00:00:17)	BPVE.1 - BPVE.1.1 BPVE.2 - BPVE.2.1 03_12_18 Combo final2.44
267:24 - 267:24	267:16 Q. you can read the 267:17 whole thing if you need to and I'll, of course, 267:18 allow you, but this involved a conference call 267:19 with the design team of the G2 filter and Chris 267:20 Ganser, caudal migrations of the G2 were briefly 267:21 discussed, that's what it says there in the 267:22 e-mail; right? 267:23 A. Yes. Ciavarella, David 11-12-2013 (00:00:01)	BPVE.2.2 03_12_18 Combo final2.45
268:4 - 268:5	267:24 Q. And what's a caudal migration? Ciavarella, David 11-12-2013 (00:00:04)	clear 03_12_18 Combo final2.46
268:6 - 268:15	268:4 A. It means downward basically, so toward 268:5 the feet. Ciavarella, David 11-12-2013 (00:00:40)	03_12_18 Combo final2.47
	268:6 Q. And from a patient safety and even 268:7 from an efficacy standpoint, why would a company 268:8 want to be concerned about caudal migrations? 268:9 A. Well, first, the filter is designed	

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268:10 with the intent of staying in place, and so 268:11 migrations in either direction would be 268:12 something that they would try to understand the 268:13 cause for that and -- you know, and also 268:14 understand if there were any possible adverse 268:15 outcomes based on a caudal migration.		
272:5 - 272:15	Ciavarella, David 11-12-2013 (00:00:18) 272:5 Q. Well, we know that the G2 is a 272:6 different design than the Recovery; right? 272:7 A. We do. 272:8 Q. And we do know that it was a different 272:9 design than the Simon Nitinol filter? 272:10 A. Yes. 272:11 Q. There was something about the design 272:12 of the G2 that for some reason you were getting 272:13 reports of a downward migration of more than 272:14 2 centimeters; correct? 272:15 A. Yes.	03_12_18 Combo final2.48
272:24 - 273:21	Ciavarella, David 11-12-2013 (00:00:55) 272:24 And this was something 272:25 that the company was recognizing early in the 273:1 marketing of the G2? 273:2 A. Yes. 273:3 Q. And, by the way, the G2 went through a 273:4 510(k), you know, process as well? 273:5 A. Yes. 273:6 Q. And it was represented to be, 273:7 therefore, substantially equivalent from safety 273:8 and efficacy to all of its predicate devices? 273:9 A. Yes. Again, you know, the regulatory 273:10 terminology, right. 273:11 equivalent to whatever predicates were used, I 273:12 presume the Recovery, but I don't -- I think it 273:13 was much closer in design to the Recovery than 273:14 it was to the Simon Nitinol. 273:15 Q. And would you agree with others that 273:16 have testified before you that it was designed 273:17 to resolve some of the issues that existed with 273:18 the Recovery filter -- 273:19 A. Yes.	03_12_18 Combo final2.49

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273:20	Q. -- migration, fracture?	
273:21	A. Those are the two biggest.	
273:22 - 274:6	Ciavarella, David 11-12-2013 (00:00:27)	03_12_18 Combo final2.50
273:22	Q. And then you write back to Cindi and	
273:23	again carbon copy Shari Allen and Gin Schulz on	
273:24	Page 1, the first -- the top page of this	
273:25	Exhibit -- what's the number again, thirty --	
274:1	A. 3.	
274:2	Q. -- 33 -- I'm going to write 33 on my	BPVE.1.2
274:3	copy -- "Thank you Cindi. I think we should	
274:4	discuss these further so I can get a better	
274:5	understanding of each one. But first, it would	
274:6	help if I had a little more information."	
274:7 - 275:6	Ciavarella, David 11-12-2013 (00:01:00)	03_12_18 Combo final2.51
274:7	Did I read that correctly?	clear
274:8	A. Uh-huh, yes.	
274:9	Q. And then you wrote: "From what you've	BPVE.1.3
274:10	sent me, it seems to me that the biggest (worst	
274:11	case) consequence of these migrations is that	
274:12	they are accompanied in a majority of cases by	
274:13	tilting."	
274:14	Do you see that?	
274:15	A. Yes.	clear
274:16	Q. And by "these migrations," you mean a	
274:17	downward -- i.e., caudal -- migration?	
274:18	A. Yes.	
274:19	Q. And we talked about tilting earlier.	
274:20	Remember that?	
274:21	A. Yes.	
274:22	Q. And what did you mean by the worst	
274:23	case/biggest consequence would be tilting?	
274:24	A. Well, what my concern with in that	
274:25	paragraph was that the filter, which is	
275:1	conically shaped when it's placed upright, as it	
275:2	fell would also turn over on its side like a	
275:3	Christmas tree when it was placed and then	
275:4	fallen over lying in the vein in a -- in a	
275:5	horizontal orientation instead of a vertical	
275:6	orientation.	
275:19 - 276:9	Ciavarella, David 11-12-2013 (00:00:44)	03_12_18 Combo final2.52

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	275:19 Q. And then you wrote: "This raises the 275:20 concern of lack of efficacy..."; right? And by 275:21 "lack of efficacy," meaning in that position the 275:22 device may not be able to stop the type of clots 275:23 that it's designed to stop and for the reason 275:24 for which it was placed? 275:25 A. That's my concern, yeah. That was it.	BPVE.1.4
	276:1 Q. In fact, you say "...to perform clot 276:2 interruption," you actually say it in this 276:3 e-mail; right? 276:4 A. Yes. 276:5 Q. While I'm thinking about it, when the 276:6 G2 was approved for marketing, it was approved 276:7 as a permanent device, not a retrievable device; 276:8 correct? 276:9 A. Correct.	clear
276:17 - 276:20	Ciavarella, David 11-12-2013 (00:00:10) 276:17 Q. So when the Recovery was removed from 276:18 the market, the company no longer had a 276:19 retrievable device that it could sell? 276:20 A. Correct.	03_12_18 Combo final2.53
276:21 - 276:23	Ciavarella, David 11-12-2013 (00:00:06) 276:21 Q. Until the G2 got its retrievable 276:22 indication about two years later; right? 276:23 A. Correct.	03_12_18 Combo final2.54
277:11 - 278:10	Ciavarella, David 11-12-2013 (00:01:00) 277:11 Q. Okay. The next sentence is: "I would 277:12 like to look more generally at the G2 277:13 complaints. I have seen problems with caudal 277:14 migration, tilting, perforation, mis-deployment 277:15 and maybe one or two additional things." 277:16 You wrote that? 277:17 A. Yes. 277:18 Q. And so in the early weeks or few 277:19 months that the product was on the market, you 277:20 were already seeing yourself personally issues 277:21 involving caudal migration, tilting, and 277:22 perforation; right? 277:23 A. Yes. 277:24 Q. And then you ask: "Can you tell me	03_12_18 Combo final2.55 BPVE.1.6 BPVE.1.7

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	277:25 the total number of complaints (not damaged 278:1 packages and the like) and total number of units 278:2 distributed?" 278:3 You asked that important question? 278:4 A. Yes. 278:5 Q. And that important question dealt with 278:6 a lot of the data we've been talking about 278:7 today, that is, how many units do we have that 278:8 are sold and how many complaints do we have from 278:9 doctors that have been using the product? 278:10 A. Right.	clear
278:13 - 278:16	Ciavarella, David 11-12-2013 (00:00:09) 278:13 Q. Why would you want that information? 278:14 A. Well, it's -- it's part of the 278:15 information that we have been collecting and 278:16 looking at all this time.	03_12_18 Combo final2.56
279:5 - 279:12	Ciavarella, David 11-12-2013 (00:00:22) 279:5 Q. I'm saying as 279:6 far as data that you requested of Cindi, you 279:7 asked her specifically for the number of MDRs 279:8 that you had for G2, the total number of 279:9 complaints, and the total number of units 279:10 distributed. That was important for you to have 279:11 to evaluate this problem? 279:12 A. Right	03_12_18 Combo final2.57
279:12 - 279:16	Ciavarella, David 11-12-2013 (00:00:11) 279:12 A. But it was just a starting 279:13 point. So then I would go on to our TrackWise 279:14 system in which details of the complaints were 279:15 entered and review all of them, which is what I 279:16 would do.	03_12_18 Combo final2.58
280:8 - 280:20	Ciavarella, David 11-12-2013 (00:00:31) 280:8 Q. And the reason you would want to know 280:9 the total number of complaints and the total 280:10 numbers of units distributed because you were 280:11 trying to see what the rate was at least based 280:12 on that data? 280:13 A. Yeah. I wanted to see what the rate 280:14 of reported events was. 280:15 Q. Because it was important from the	03_12_18 Combo final2.59

Page/Line	Source	ID
280:21 - 280:23	<p>280:16 standpoint of whether or not this device may 280:17 have a unique design problem or may be 280:18 unnecessarily exposing patients to a risk that 280:19 you didn't realize existed with the product; 280:20 right?</p> <p>Ciavarella, David 11-12-2013 (00:00:03)</p> <p>280:21 A. Well, I mean, eventually -- 280:22 Q. Is that yes or no? You can't answer 280:23 that yes or no?</p>	03_12_18 Combo final2.60
281:1 - 281:1	<p>Ciavarella, David 11-12-2013 (00:00:01)</p> <p>281:1 THE WITNESS: Well, yes.</p>	03_12_18 Combo final2.61
281:4 - 281:8	<p>Ciavarella, David 11-12-2013 (00:00:09)</p> <p>281:4 A. I mean, eventually that's the outcome 281:5 of my investigation, to try to get that 281:6 information. When I first asked -- asked for 281:7 it, it's just to put the number of events into 281:8 context.</p>	03_12_18 Combo final2.62
281:9 - 283:19	<p>Ciavarella, David 11-12-2013 (00:03:24)</p> <p>281:9 Q. The G -- then you state at the bottom: 281:10 "The G2 is a permanent filter; we also have one 281:11 (the SNF) that has virtually no complaints 281:12 associated with it. Why shouldn't doctors be 281:13 using that one rather than the G2?" 281:14 You asked that question? 281:15 A. Uh-huh. 281:16 Q. Why did you ask that question or is 281:17 the question pretty obvious? 281:18 A. Well, I mean, the question is obvious 281:19 in terms of I'm saying the G2 is a permanent 281:20 filter, the SNF is a permanent filter, we've had 281:21 very few complaints. It was a request for 281:22 information. I mean, I'd have to say it was 281:23 probably a -- in looking back on it now naive on 281:24 my part or lack of familiarity with the SNF 281:25 other than these tables and things which listed 282:1 reports. So -- 282:2 Q. Well, you were suggesting that -- you 282:3 know, that if you have another device available 282:4 to you that was potentially safer and could 282:5 perform as well as or better than the G2, why</p>	03_12_18 Combo final2.63 CIAVARELLA33.1.1 clear

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282:6 even sell the G2 right now until we resolve some
 282:7 of these issues? Weren't you suggesting that?
 282:8 A. Yeah, that's what I would conclude.
 282:9 Q. And then you also ask: "Can you also
 282:10 send me the total" complaint rates --
 282:11 "complaints rate and MDR complaint rate for
 282:12 SNF?"
 282:13 You asked for that?
 282:14 A. Right, because I didn't know very much
 282:15 about the SNF. That's why I asked for the
 282:16 rates. And I think that Bard has a process by
 282:17 which all of the TrackWise complaints would be
 282:18 sent to me by e-mail as well as several other
 282:19 people, such as Mr. Ganzer and Mr. Barry. So in
 282:20 the past year or so I would see complaints
 282:21 related to the Recovery filter, I would see
 282:22 complaints related to the G2 filter, but I
 282:23 didn't see any complaints related to the SNF.
 282:24 So, you know, I had no idea how much
 282:25 was sold, you know, what were the pros and cons
 283:1 of using it, what were the different situations.
 283:2 So that sort of explains my naive question but
 283:3 also why I wanted to get more information about
 283:4 the complaint rate for the Simon Nitinol.
 283:5 Q. But you thought, at least as of
 283:6 December 23rd, 2005, that a good exercise for
 283:7 you as the medical affairs director would be to
 283:8 see how the G2 in its short period on the market
 283:9 compares from a complication and risk standpoint
 283:10 to the Simon Nitinol filter?
 283:11 A. Yeah, I wanted to -- I wanted to make
 283:12 that comparison that -- I guess comparison's the
 283:13 right word between the filters as part of my
 283:14 review of the adverse event profile of the G2.
 283:15 Q. Did someone prepare a report like that
 283:16 for you?
 283:17 A. You know, I don't remember. I don't
 283:18 think that -- I don't think they would ignore
 283:19 it, you know, my question.

BPVE.1.8

clear

clear

287:16 - 287:24

Ciavarella, David 11-12-2013 (00:00:42)

03_12_18 Combo final2.64

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	287:16 Q. So No. 35 will be your related health	CIAVARELLA35.1.1
	287:17 hazard evaluation dated December 17, 2004.	
	287:18 just confirm for us that that's the health	CIAVARELLA35.1
	287:19 hazard evaluation that you prepared as part of	
	287:20 your duties as the medical director and within	
	287:21 which -- from which you gained information and	
	287:22 knowledge from having read Dr. Lehmann's report	
	287:23 dated December 15.	
	287:24 A. Yes.	
294:2 - 294:16	Ciavarella, David 11-12-2013 (00:00:48)	03_12_18 Combo final2.67
	294:2 If you look at Page 2 -- well, it's	clear
	294:3 not Page 2. It's actually Page 3 of the	
	294:4 exhibit. And there's reference there to	
	294:5 Dr. Scott Trerotola. Do you know Dr. Trerotola?	CIAVARELLA36.3.1
	294:6 A. Yes, I've met him.	
	294:7 Q. He's Stanley Baum professor of	
	294:8 radiology, University of Pennsylvania, chief	
	294:9 interventional radiologist in Philadelphia.	
	294:10 Do you see that?	
	294:11 A. Yes.	clear
	294:12 Q. And does -- assuming that the G1A is,	
	294:13 in fact, the G2 filter, is Dr. Trerotola telling	
	294:14 the company as of February 2005 that he is still	CIAVARELLA36.3.2
	294:15 very concerned about fracture with that device?	
	294:16 A. Yeah	
294:18 - 294:20	Ciavarella, David 11-12-2013 (00:00:07)	03_12_18 Combo final2.68
	294:18 THE WITNESS: It appeared that	clear
	294:19 that's what Janet Hudnall recorded from her	
	294:20 conversations with him.	
351:16 - 351:20	Ciavarella, David 11-12-2013 (00:00:16)	03_12_18 Combo final2.69
	351:16 Q. Here's No. 39. No. 39 is a June --	
	351:17 July 9 HHE again authored by David Ciavarella	CIAVARELLA39.1.1
	351:18 regarding limb fractures of Recovery filter. Do	
	351:19 you see that?	
	351:20 A. I do.	
353:10 - 353:14	Ciavarella, David 11-12-2013 (00:00:13)	03_12_18 Combo final2.70
	353:10 Q. so this deals with 17	CIAVARELLA39.1.6
	353:11 reports of limb fractures from the time period	
	353:12 July -- January 2002 through June 2004; is that	
	353:13 right?	

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353:22 - 354:3	<p>353:14 A. Yes.</p> <p>Ciavarella, David 11-12-2013 (00:00:32)</p> <p>353:22 Q. And you calculated from just this</p> <p>353:23 information, recognizing underreporting and such</p> <p>353:24 but at least from the actual data that the</p> <p>353:25 company had, that the fracture rate was 1 per</p> <p>354:1 600 or 0.2 percent; is that right? Do you see</p> <p>354:2 that?</p> <p>354:3 A. Yes.</p>	<p>03_12_18 Combo final2.71</p> <p>CIAVARELLA39.1.7</p>
354:18 - 356:11	<p>Ciavarella, David 11-12-2013 (00:02:04)</p> <p>354:18 Q. "In the second symptomatic case, the</p> <p>354:19 patient presented with sudden shortness of</p> <p>354:20 breath and syncope."</p> <p>354:21 Syncope is what?</p> <p>354:22 A. Loss of consciousness.</p> <p>354:23 Q. "Hemopericardium and cardiac</p> <p>354:24 arrhythmia were diagnosed."</p> <p>354:25 Do you see that?</p> <p>355:1 A. I do.</p> <p>355:2 Q. Those are serious potentially</p> <p>355:3 catastrophic events; would you agree?</p> <p>355:4 A. Yes.</p> <p>355:5 Q. "A detached filter arm was noted in</p> <p>355:6 the ventricular wall, and it was removed during</p> <p>355:7 open heart surgery."</p> <p>355:8 Did I read that correctly?</p> <p>355:9 A. Yes.</p> <p>355:10 Q. So what has been concluded here is</p> <p>355:11 that one of these 17 fractures that were</p> <p>355:12 reported carried with it symptoms and a</p> <p>355:13 condition that could have very readily killed</p> <p>355:14 the patient?</p> <p>355:15 A. Yes.</p> <p>355:16 Q. As a matter of fact, just having to</p> <p>355:17 have open heart surgery puts the patient at risk</p> <p>355:18 of death; right?</p> <p>355:19 A. It does.</p> <p>355:20 Q. And you further report that there were</p> <p>355:21 20 arm fragments reported in 14 cases, meaning</p> <p>355:22 there were actually more than one arm fragment</p>	<p>03_12_18 Combo final2.72</p> <p>CIAVARELLA39.1.8</p> <p>clear</p>

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355:23 that fractured in some instances?

355:24 A. Yes.

355:25 Q. And in six of the patients the

356:1 detached arm migrated to the heart or lungs;

356:2 right?

356:3 A. Yes.

356:4 Q. And, by the way, the other fractures

356:5 that didn't migrate to the heart or lung or

356:6 cause, you know, hemopericardium and cardiac

356:7 arrhythmia and open heart surgery, the mere fact

356:8 that the limb fractured still put the patients

356:9 at the potential risk of those occurrences; am I

356:10 right about that?

356:11 A. Yes.

356:16 - 356:19

Ciavarella, David 11-12-2013 (00:00:07)

03_12_18 Combo final2.73

356:16 Q. Now, down at the bottom: "The root

356:17 cause of the fractures has not been determined,"

356:18 do you see where I am?

356:19 A. Yes.

357:4 - 357:23

Ciavarella, David 11-12-2013 (00:00:47)

03_12_18 Combo final2.74

357:4 Q. Let me ask you, when you read that,

357:5 didn't you think to yourself we might have a

357:6 design issue with this product, it may not be

357:7 designed in the manner in which we intended and

357:8 expected it to perform from a fracture

357:9 standpoint?

357:10 A. Well, yes, I wrote the sentence

357:11 because I thought it might be relevant to the

357:12 root cause.

357:13 Q. Did you tell physicians -- by the way,

357:14 after the June HHE, did word go out, an eBlast,

357:15 information to salespeople giving them the

357:16 precise information about what the company was

357:17 seeing with other physicians' experiences with

357:18 the Recovery filter from the standpoint of

357:19 migrations and migration deaths?

357:20 A. I don't know.

357:21 Q. How about with respect to these

357:22 fractures?

357:23 A. Yeah, again, I don't know.

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358:2 - 358:9	Ciavarella, David 11-12-2013 (00:00:22) 358:2 Q. Do you know whether or not physicians 358:3 who were making risk/benefit assessments and 358:4 having informed consent discussions with their 358:5 patients might want to know whether or not there 358:6 have been 12 full filter migrations, four of 358:7 them resulting in death and two resulting in 358:8 open heart surgery, they'd want to know that 358:9 before they decide to use that filter?	03_12_18 Combo final2.75
358:12 - 358:13	Ciavarella, David 11-12-2013 (00:00:03) 358:12 THE WITNESS: I don't know that 358:13 they weren't aware of it.	03_12_18 Combo final2.76
358:15 - 358:20	Ciavarella, David 11-12-2013 (00:00:24) 358:15 Q. Well, I mean, how would they become 358:16 aware of them if the company didn't tell them? 358:17 A. Well, two things: One, they were 358:18 reported on the MAUDE database. Secondly, the 358:19 instructions for use contained information about 358:20 migrations and fractures.	03_12_18 Combo final2.77
358:22 - 359:1	Ciavarella, David 11-12-2013 (00:00:14) 358:22 Do you know if 358:23 the company put out any type of information, 358:24 precise information, that describes the events 358:25 that you describe in your HHE in June of 2004? 359:1 A. Not that I recall.	03_12_18 Combo final2.78
359:14 - 359:20	Ciavarella, David 11-12-2013 (00:00:21) 359:14 Q. On this team that is looking 359:15 at this -- these issues, migration and fracture 359:16 and the potential catastrophic event in 359:17 patients, is there anyone else on this team 359:18 that's a medical doctor besides David 359:19 Ciavarella? 359:20 A. No.	03_12_18 Combo final2.79
359:24 - 360:6	Ciavarella, David 11-12-2013 (00:00:23) 359:24 Q. And let's look at the "Nature & 359:25 Seriousness of the Risk: The effect of filter 360:1 fracture is no" -- "The effect of filter 360:2 fracture is no discernible effect in most cases. 360:3 Serious injury or even sudden death may occur in 360:4 rare cases."	03_12_18 Combo final2.80 CIAVARELLA39.2.5

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360:5 Right?		
360:6 A. Yes.		
360:25 - 361:5	Ciavarella, David 11-12-2013 (00:00:13)	03_12_18 Combo final2.81
360:25 Q. "Likelihood of Occurrence of the		CIAVARELLA39.2.6
361:1 Problem," you wrote: No well-controlled trials		
361:2 exist to answer this question definitively for		
361:3 other filters.		
361:4 You wrote that?		
361:5 A. Yes.		
362:6 - 363:16	Ciavarella, David 11-12-2013 (00:01:52)	03_12_18 Combo final2.82
362:6 Q. The very last sentence I believe on		
362:7 Page 3 you wrote: "However, there is no way to		CIAVARELLA39.3.1
362:8 predict which patients will develop this		
362:9 complication. More frequent monitoring of the		CIAVARELLA39.4.1
362:10 filter once placed may facilitate discovery of		
362:11 abnormal placement (a possible but not proven		
362:12 predisposing factor for fracture) or indeed of a		
362:13 fractured filter, but could not prevent all		
362:14 potential adverse events."		
362:15 You wrote that; right?		
362:16 A. I did.		
362:17 Q. Did the company ever engage on a		clear
362:18 recommendation to physicians either with a "Dear		
362:19 Doctor" letter, a change in the IFU, eBlasts,		
362:20 information given to their salespeople that it		
362:21 was time for doctors to start monitoring the		
362:22 Recovery filter once placed to see if they		
362:23 could -- they might be able to find fractures?		
362:24 A. I don't know.		
362:25 Q. Wouldn't that have been a good idea		
363:1 had the only doctor working on this case had		
363:2 recommended it?		
363:3 A. Not necessarily.		
363:4 Q. But that was something that you		
363:5 recommended in July of 2004 and, as far as you		
363:6 know, the company did not do that; right?		
363:7 A. I wouldn't say that I recommended it.		
363:8 Q. Did you think it was a good idea?		
363:9 A. I think I just put it out there as a		
363:10 potential suggestion or something to think		

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	363:11 about.	
	363:12 Q. Something that could potentially save	
	363:13 people from a fracture or device migrating to	
	363:14 the heart if you could catch it early in that	
	363:15 phase?	
	363:16 A. You know, my words are what they are.	
364:4 - 364:5	Ciavarella, David 11-12-2013 (00:00:09)	03_12_18 Combo final2.83
	364:4 Q. Exhibit 40 is a February 15, 2006, HHE	CIAVARELLA40.1.1
	364:5 authored by Dr. Ciavarella	
364:14 - 365:2	Ciavarella, David 11-12-2013 (00:00:51)	03_12_18 Combo final2.84
	364:14 Q. And you report that -- and this is	CIAVARELLA40.1
	364:15 February 2006. The G2 had been on the market	
	364:16 for approximately, what, four or five months?	
	364:17 A. Yeah, probably. I don't remember	
	364:18 exactly.	
	364:19 Q. There had been ten reports of	CIAVARELLA40.1.3
	364:20 migration, one cephalad and nine caudal, as of	
	364:21 February 9, 2006; correct?	
	364:22 A. Yes.	
	364:23 Q. And your conclusion is that "the	
	364:24 Severity of this hazard is Critical, due to the	
	364:25 possibility of alteration of primary function as	
	365:1 a result of the migration events"; right?	
	365:2 A. Yes.	
366:1 - 366:19	Ciavarella, David 11-12-2013 (00:00:53)	03_12_18 Combo final2.85
	366:1 You write that "...unlike literature	CIAVARELLA40.1.4
	366:2 reports, the migration events with the G2 filter	
	366:3 have been associated with a high percentage of	
	366:4 caudal" migration -- "migrations accompanied by	
	366:5 significant filter tilting and limb	
	366:6 displacement," and that there was a single case	
	366:7 of fatal pulmonary embolus, clinically	
	366:8 diagnosed, in a patient with a G2 filter	
	366:9 reported.	
	366:10 Do you see that?	
	366:11 A. I do.	
	366:12 Q. And did you write that in there	
	366:13 because of the way	
	366:14 the device tilted, it didn't prevent the	
	366:15 pulmonary embolism?	

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369:2 - 369:6	<p>366:16 A. That was my potential possibility of</p> <p>366:17 alteration of pulmonary function, meaning it</p> <p>366:18 wouldn't stop a clot. So the reported rate of</p> <p>366:19 pulmonary embolism is -- was relevant to that.</p> <p>Ciavarella, David 11-12-2013 (00:00:13)</p> <p>369:2 "Likelihood of Occurrence of the Problem." You</p> <p>369:3 have the rate at 0.16 percent, meaning the</p> <p>369:4 likelihood of there being a filter migration</p> <p>369:5 with the G2, most of which would be caudal?</p> <p>369:6 A. Uh-huh.</p>	<p>03_12_18 Combo final2.86</p> <p>CIAVARELLA40.2.1</p>
369:18 - 369:24	<p>Ciavarella, David 11-12-2013 (00:00:17)</p> <p>369:18 Q. In fact, you even say after that</p> <p>369:19 .16 percent that "The actual rate is probably</p> <p>369:20 higher than this, due to the asymptomatic nature</p> <p>369:21 of some of the migration events and because the</p> <p>369:22 actual number of G2 filters implanted is very</p> <p>369:23 probably less than the number distributed."</p> <p>369:24 A. Yes.</p>	<p>03_12_18 Combo final2.87</p> <p>CIAVARELLA40.2.2</p>
370:3 - 370:10	<p>Ciavarella, David 11-12-2013 (00:00:31)</p> <p>370:3 Q. And then you wrote "Likelihood of Harm</p> <p>370:4 if the Problem Occurs:" "No serious injuries</p> <p>370:5 have occurred, although the need for filter</p> <p>370:6 removal and placement of alternative filters in</p> <p>370:7 many cases points out the potential for harm if</p> <p>370:8 a migration event is not discovered and</p> <p>370:9 treated"; right?</p> <p>370:10 A. Yes.</p>	<p>03_12_18 Combo final2.88</p> <p>CIAVARELLA40.2.3</p> <p>CIAVARELLA40.3.1</p>
370:19 - 370:23	<p>Ciavarella, David 11-12-2013 (00:00:12)</p> <p>370:19 Q. And then other alternatives available,</p> <p>370:20 you agree that there are both alternative</p> <p>370:21 permanent and retrievable IVC filters that exist</p> <p>370:22 as an alternative to the G2?</p> <p>370:23 A. Yes.</p>	<p>03_12_18 Combo final2.89</p> <p>clear</p>

Plaintiffs Designations = 00:20:49

Defense Designations = 00:08:35

P & D Affirmatives = 00:09:54

Total Time = 00:39:18

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Documents Shown

BPVE

CIAVARELLA21

CIAVARELLA28

CIAVARELLA33

CIAVARELLA35

CIAVARELLA36

CIAVARELLA39

CIAVARELLA40

EXHIBIT B

Designation Run Report

Wong 10-18-16 Booker Depo Designations final3

Wong, Natalie 10-18-2016

Plaintiffs Designations 01:03:46

Defense Designations 00:13:03

Plaintiffs and Defense Designations 00:03:51

Total Time 01:20:40



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8:10 - 8:12	Wong, Natalie 10-18-2016 (00:00:03) 8:10 Q. Hey, good morning, ma'am. Will you please 8:11 tell us your name? 8:12 A. Natalie Wong.	03_16_18 Combo final3.1
10:3 - 10:6	Wong, Natalie 10-18-2016 (00:00:10) 10:3 Q. What is your educational background? Can 10:4 you give us just a quick snapshot? 10:5 A. Sure. I have a bachelor's of engineering 10:6 from ASU. And I have an MBA from ASU.	03_16_18 Combo final3.2
10:7 - 10:16	Wong, Natalie 10-18-2016 (00:00:29) 10:7 Q. Any particular kind of engineering? 10:8 A. Industrial. 10:9 Q. And what does industrial engineering 10:10 entail? 10:11 A. The first two years is the same as any 10:12 other engineering curriculum, it's the basic statics, 10:13 dynamics, statistics, Engineering 101. And then the 10:14 upper-level classes are more towards quality, 10:15 production, molding, simulation, those type of 10:16 courses.	03_16_18 Combo final3.3
13:6 - 13:8	Wong, Natalie 10-18-2016 (00:00:03) 13:6 Q. Is calculating statistical significance 13:7 something you know how to do? 13:8 A. Yes.	03_16_18 Combo final3.4
14:19 - 14:25	Wong, Natalie 10-18-2016 (00:00:10) 14:19 Did you meet with counsel in preparation 14:20 for your deposition? 14:21 A. Yes. 14:22 Q. On how many occasions? 14:23 A. Three. 14:24 Q. About how long were each of those meetings? 14:25 A. Maybe around three hours.	03_16_18 Combo final3.5
17:10 - 17:15	Wong, Natalie 10-18-2016 (00:00:12) 17:10 You're currently employed with Bard 17:11 Peripheral Vascular; is that correct? 17:12 A. Yes. 17:13 Q. And what is your current position? 17:14 A. I'm quality engineering manager for new 17:15 product development under biopsy products.	03_16_18 Combo final3.6
19:22 - 20:3	Wong, Natalie 10-18-2016 (00:00:10)	03_16_18 Combo final3.7

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19:22 Q. So is your involvement, at this point,
19:23 primarily with the up-front testing of a product to
19:24 make sure it's safe before it's launched?

19:25 A. Yes.

20:1 Q. And is that bench testing and things like
20:2 that?

20:3 A. Yes.

20:4 - 20:12

Wong, Natalie 10-18-2016 (00:00:30)

03_16_18 Combo final3.8

20:4 Q. what is a DFMEA?

20:5 A. It stands for design, failure, modes,
20:6 effects and analysis and we go through an entire
20:7 procedure and help identify what are the risks that
20:8 can occur. The severity of the risk to the patient
20:9 or physician? What causes occurred. What type of
20:10 things could have occur that would result in a
20:11 certain failure mode. What controls we have in place
20:12 to mitigate those risks.

20:14 - 20:16

Wong, Natalie 10-18-2016 (00:00:04)

03_16_18 Combo final3.9

20:14 what's Bard really use that for?

20:15 A. To identify failure modes and risks to the
20:16 patient.

20:17 - 20:21

Wong, Natalie 10-18-2016 (00:00:13)

03_16_18 Combo final3.10

20:17 Q. Okay. And what happens if a -- if a risk
20:18 to the patient or failure mode is identified? What
20:19 happens from there?

20:20 A. We do -- we identify the appropriate
20:21 testing to mitigate that risk.

22:23 - 23:21

Wong, Natalie 10-18-2016 (00:01:01)

03_16_18 Combo final3.11

22:23 Q. And if a new failure mode is identified
22:24 and -- and you're in the process of updating the
22:25 DFMEA, what is done with regard to that product
23:1 that's already being sold?

23:2 A. That would need to go through the
23:3 investigation process.

23:4 Q. Well, what if -- what if a product is
23:5 already being sold and the updated DFMEA shows that
23:6 it's in a Quad 3, for example? What -- what would
23:7 happen from that point?

23:8 A. We would need to evaluate it. We would
23:9 need to investigate it, and understand what it means.

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23:10 Q. Okay. What is done during that evaluation
 23:11 to -- to warn physicians and patients about the fact
 23:12 that -- that this new failure mode has been
 23:13 identified, and that there's additional testing being
 23:14 done?

23:15 A. I think, first off, we need to understand
 23:16 what the failure mode is. We need to investigate it.
 23:17 We need to, as part of the investigation, we would
 23:18 probably request an HHE, a Health Hazard Evaluation.
 23:19 And all those inputs coming together into, you know,
 23:20 what we call our CAPA system right now. And that
 23:21 would go through management approval.

23:25 - 24:9

Wong, Natalie 10-18-2016 (00:00:21)

03_16_18 Combo final3.12

23:25 Q. My question is a little different. What is
 24:1 done to let the physicians and patients know that
 24:2 there is this new failure mode that warrants further
 24:3 investigation by the -- by the company? What's --
 24:4 what's done to let them know about that while that's
 24:5 going on?

24:6 A. We don't know what it is yet. We don't
 24:7 know what this new failure mode is. We need to do a
 24:8 thorough investigation to understand what it is
 24:9 before we communicate anything.

24:10 - 24:15

Wong, Natalie 10-18-2016 (00:00:11)

03_16_18 Combo final3.13

24:10 Q. Well, you've got a failure mode that you're
 24:11 looking into, and you've already figured out that
 24:12 it's a Quad 3, and it needs to be looked into further
 24:13 to see what's causing it, so -- right? I mean you've
 24:14 got that --

24:15 A. Sure.

26:17 - 26:23

Wong, Natalie 10-18-2016 (00:00:16)

03_16_18 Combo final3.14

26:17 Q. So and that's something -- and that
 26:18 is information, for example, "We've identified a new
 26:19 failure mode. We're looking into it," that's
 26:20 information that, to the best of your knowledge, is
 26:21 not passed on to physicians by Bard. Correct?

26:22 A. Not in the initial stages of an
 26:23 investigation.

26:24 - 27:1

Wong, Natalie 10-18-2016 (00:00:06)

03_16_18 Combo final3.15

26:24 Q. Are the results of a DFMEA analysis

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26:25 important?

27:1 A. Yes. Absolutely.

27:2 - 27:6

Wong, Natalie 10-18-2016 (00:00:12)

03_16_18 Combo final3.16

27:2 Q. Why?

27:3 A. Because you identified the severity of the
 27:4 failure modes. You know, you -- it identifies the
 27:5 failure modes that could potentially occur in the
 27:6 device before you launch.

27:7 - 27:11

Wong, Natalie 10-18-2016 (00:00:12)

03_16_18 Combo final3.17

27:7 Q. And if it ends up in, for example, a Quad 3
 27:8 or a Quad 4, what does that mean?

27:9 A. It means that it's a high -- it's an
 27:10 alarming -- it's a high issue that we need to look at
 27:11 more deeply.

27:12 - 27:15

Wong, Natalie 10-18-2016 (00:00:09)

03_16_18 Combo final3.18

27:12 Q. Okay.

27:13 A. You know, and do we have the controls to
 27:14 mitigate that risk? Can we reduce that risk from a
 27:15 Quad 3 to a Quad 2?

27:16 - 27:25

Wong, Natalie 10-18-2016 (00:00:23)

03_16_18 Combo final3.19

27:16 Q. And if you've got -- if you've got
 27:17 something that ends up in a Quad 3 or Quad 4, that's
 27:18 something that Bard needs to take action on. Right?

27:19 A. On a team level, yes, before we launch.

27:20 Q. Or if it's something that's -- that's
 27:21 already been launched, and it's a new failure mode,
 27:22 same deal, right, something they need to take action
 27:23 on?

27:24 A. They need to evaluate and determine what
 27:25 the action would be, yes.

28:15 - 28:20

Wong, Natalie 10-18-2016 (00:00:19)

03_16_18 Combo final3.20

28:15 as part of the DFMEA

28:16 analysis, is a root cause analysis performed for --
 28:17 for various failure modes?

28:18 A. It's kind of built in, in a way, because
 28:19 you identify the causes of failure for a certain
 28:20 failure mode within the DFMEA.

29:17 - 29:25

Wong, Natalie 10-18-2016 (00:00:22)

03_16_18 Combo final3.21

29:17 Q. Okay. And what do you -- what do you mean
 29:18 when you say "failure mode," just so the jury

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29:19 understands?

29:20 A. So something that happens, you know, if a

29:21 product -- you know, if something didn't work

29:22 correctly, as the physician intended.

29:23 Q. Okay. Or as the manufacturer intended.

29:24 Right?

29:25 A. Or the manufacturer intended, yes.

32:13 - 32:16

Wong, Natalie 10-18-2016 (00:00:07)

03_16_18 Combo final3.22

32:13 Q. why does Bard do root cause

32:14 analysis, I mean, what's their -- why do they do

32:15 them?

32:16 A. To prevent failure modes from occurring.

32:17 - 32:19

Wong, Natalie 10-18-2016 (00:00:05)

03_16_18 Combo final3.23

32:17 Q. And is that something that's important to

32:18 do?

32:19 A. Yes, absolutely.

32:20 - 32:22

Wong, Natalie 10-18-2016 (00:00:04)

03_16_18 Combo final3.24

32:20 Q. why is it important?

32:21 A. Because we don't want complaints. We don't

32:22 want patient injury.

32:23 - 33:20

Wong, Natalie 10-18-2016 (00:00:49)

03_16_18 Combo final3.25

32:23 Q. It's important to understand the root cause

32:24 of failure modes to prevent injury to patients.

32:25 Fair?

33:1 A. Yes.

33:2 Q. And safety of the patients is first and

33:3 foremost for manufacturing companies. Right?

33:4 A. Yes.

33:5 Q. And -- and Bard feels that way?

33:6 A. Yes.

33:7 Q. So as of today, has Bard determined the

33:8 root cause of filter fracture?

33:9 A. I don't know. I haven't been on filters

33:10 the last several years.

33:11 Q. As of the time you left filters in -- in

33:12 2012, has Bard figured out the root cause of filter

33:13 fracture?

33:14 A. No, not that I know of.

33:15 Q. How about filter migration?

33:16 A. No, not that I know of.

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33:17 Q. How about perforations?

33:18 A. Not that I know of.

33:19 Q. How about tilt?

33:20 A. Not that I know of, no.

34:1 - 34:6

Wong, Natalie 10-18-2016 (00:00:15)

03_16_18 Combo final3.26

34:1 Q. Bard continues to sell, despite not having

34:2 identified a root cause of -- of the failures of --

34:3 of its failure modes, its IVC filters for placement

34:4 in veins in patients -- in a vein that leads directly

34:5 to the heart and lungs?

34:6 A. Yes.

34:20 - 34:24

Wong, Natalie 10-18-2016 (00:00:15)

03_16_18 Combo final3.27

34:20 Q. Do you think that the fact that Bard has

34:21 not now, in 12 years of selling its filters, been

34:22 able to identify the root cause of the failure modes

34:23 associated with those filters, is something a

34:24 physician would want to know?

35:6 - 35:20

Wong, Natalie 10-18-2016 (00:00:30)

03_16_18 Combo final3.28

35:6 Yeah, I think physicians should know, and I

35:7 think we do communicate through the IFU.

35:8 BY MR. DEGREEFF:

35:9 Q. So you believe that in the IFU it states

35:10 that Bard has failed to identify the root cause of

35:11 the failure modes?

35:12 A. Sorry, no, not that part.

35:13 Q. Okay. As far as you know, has it ever been

35:14 communicated to physicians that Bard has been unable

35:15 to identify the root cause of the failure modes

35:16 associated with its filters?

35:17 A. I don't know what's been communicated.

35:18 Q. As you sit here, are you aware of that

35:19 occurring?

35:20 A. No.

39:15 - 39:17

Wong, Natalie 10-18-2016 (00:00:03)

03_16_18 Combo final3.29

39:15 were you tracking and trending complaints and

39:16 adverse events?

39:17 A. Yes.

40:7 - 40:10

Wong, Natalie 10-18-2016 (00:00:12)

03_16_18 Combo final3.30

40:7 Q. As a quality engineering manager, did

40:8 you -- did you from -- well, were you involved with

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41:24 - 42:1	<p>40:9 filters as the quality engineering manager?</p> <p>40:10 A. Yes. I was involved with all BPV products.</p> <p>Wong, Natalie 10-18-2016 (00:00:10)</p> <p>41:24 What adverse event data did you consider in</p> <p>41:25 the tracking and trending?</p>	03_16_18 Combo final3.31
42:5 - 42:7	<p>42:1 A. We cons -- we considered all data.</p> <p>Wong, Natalie 10-18-2016 (00:00:04)</p> <p>42:5 Q. Where did you get the adverse</p> <p>42:6 event data from?</p>	03_16_18 Combo final3.32
42:12 - 42:18	<p>42:7 A. The complaint system.</p> <p>Wong, Natalie 10-18-2016 (00:00:24)</p> <p>42:12 Q. And would it also include MAUDE data?</p> <p>42:13 A. It -- so the complaints were reported to us</p> <p>42:14 and we entered them into TrackWise, which is our</p> <p>42:15 complaint-handling system. And in the system we</p> <p>42:16 would identify whether or not it was an adverse</p> <p>42:17 event. If it was an adverse event, then we reported</p> <p>42:18 it to the FDA, which gets rolled into the MAUDE.</p>	03_16_18 Combo final3.33
42:19 - 43:2	<p>Wong, Natalie 10-18-2016 (00:00:14)</p> <p>42:19 Q. So the data you were looking</p> <p>42:20 at was essentially inclusive of MAUDE?</p> <p>42:21 A. Yes.</p> <p>42:22 Q. Is that a fair way to put it?</p> <p>42:23 A. Yes.</p> <p>42:24 Q. So it was everything that was reported to</p> <p>42:25 the company which ultimately would translate into</p> <p>43:1 MAUDE?</p>	03_16_18 Combo final3.34
43:14 - 43:18	<p>43:2 A. Yes.</p> <p>Wong, Natalie 10-18-2016 (00:00:11)</p> <p>43:14 Q. And why is it important to --to</p> <p>43:15 track and trend the complaint data?</p> <p>43:16 A. To understand if something is going on</p> <p>43:17 that's unusual, so we can mitigate those type of</p> <p>43:18 complaints.</p>	03_16_18 Combo final3.35
43:18 - 44:1	<p>Wong, Natalie 10-18-2016 (00:00:19)</p> <p>43:18 complaints. What if all of a sudden we got a spike</p> <p>43:19 in a certain type of complaint for a certain failure</p> <p>43:20 mode, we would want to go and investigate that.</p> <p>43:21 Q. And why is it important to investigate</p> <p>43:22 failure modes?</p>	03_16_18 Combo final3.36

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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43:23 A. So we -- so we prevent future occurrence of
43:24 these complaints.

43:25 Q. And is that for -- for patient safety?

44:1 A. For patient safety, yes.

44:5 - 44:9

Wong, Natalie 10-18-2016 (00:00:14)

03_16_18 Combo final3.37

44:5 In your experience, what should Bard do if
44:6 it sees a -- an issue with a -- with a failure mode
44:7 when it's tracking and trending?

44:8 A. We usually initiate a complaint to further
44:9 investigate why it's occurring.

47:6 - 47:19

Wong, Natalie 10-18-2016 (00:00:28)

03_16_18 Combo final3.38

47:6 when Bard's doing its
47:7 internal tracking and trending for -- for failure
47:8 modes, that's -- the data that's available is the
47:9 complaint data. Fair?

47:10 A. Yes.

47:11 Q. And that's what Bard has to go on. Right?

47:12 A. Yes.

47:13 Q. And that's what Bard -- and Bard uses that
47:14 data with all of its devices, not just filters.
47:15 Right?

47:16 A. Yes.

47:17 Q. And is that data that's important for Bard
47:18 to review and understand?

47:19 A. Yes.

49:1 - 49:5

Wong, Natalie 10-18-2016 (00:00:11)

03_16_18 Combo final3.39

49:1 When you were working on IVC filters, was
49:2 there ever a literature review performed to see
49:3 what -- what adverse events were -- were referenced
49:4 in those -- in that literature?

49:5 A. When I was on the project team, yes.

49:11 - 49:14

Wong, Natalie 10-18-2016 (00:00:08)

03_16_18 Combo final3.40

49:11 Q. So any of the literature adverse events
49:12 that Bard was aware of, would end up in the MAUDE
49:13 database?

49:14 A. Yes.

49:16 - 49:25

Wong, Natalie 10-18-2016 (00:00:26)

03_16_18 Combo final3.41

49:16 So outside of the information that -- that
49:17 would ultimately end up in the complaint file and
49:18 then the MAUDE database, was there any other source

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49:19 of adverse -- adverse events that were considered by
49:20 Bard in doing its tracking and trending analysis?

49:21 A. No, I can't think of any.

49:22 Q. And that would be -- and that would be the
49:23 way that Bard does it on all of its -- all of its
49:24 products, devices. Right?

49:25 A. Yes.

50:11 - 50:23

Wong, Natalie 10-18-2016 (00:00:24)

03_16_18 Combo final3.42

50:11 Q. Is it fair to say

50:12 that that data is important to Bard?

50:13 A. Yes.

50:14 Q. And why is that data important to Bard?

50:15 A. Because it's -- it's telling us what's

50:16 going on in the field, you know, whether or not

50:17 patients are getting injured, you know, what failure

50:18 modes are happening with our products.

50:19 Q. And is that -- is that data that -- that

50:20 data that goes through TrackWise and ultimately ends

50:21 up in MAUDE, is that something that -- that you feel

50:22 that Bard should be paying attention to?

50:23 A. Yes.

51:4 - 51:14

Wong, Natalie 10-18-2016 (00:00:34)

03_16_18 Combo final3.43

51:4 Q. Is it something that Bard should be --

51:5 should be -- if it sees an issue with the -- with a

51:6 failure mode, that it should take action to try to

51:7 correct it?

51:8 A. Yes, as much as we can.

51:9 Q. Okay. And are the risks -- are the risks

51:10 identified by Bard with regard to that -- that

51:11 information that goes through TrackWise and into the

51:12 MAUDE database, are those -- is that important

51:13 information for Bard to consider?

51:14 A. Yes.

52:5 - 52:9

Wong, Natalie 10-18-2016 (00:00:16)

03_16_18 Combo final3.44

52:5 Q. in doing that,

52:6 something they should take into consideration and act

52:7 on, is the adverse event data that you do -- that you

52:8 do the tracking and trending on?

52:9 A. Yes, we analyze that all the time, yeah.

52:16 - 52:18

Wong, Natalie 10-18-2016 (00:00:04)

03_16_18 Combo final3.45

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52:16 Q. That data is important to patient safety.

52:17 Fair?

52:18 A. Yes.

58:5 - 58:19

Wong, Natalie 10-18-2016 (00:00:39)

03_16_18 Combo final3.46

58:5 Q. Bard often looks at the statistical

58:6 significance of an -- an increased risk. Correct?

58:7 A. That's one of the ways that we look at it.

58:8 Q. It's one of the things they look at?

58:9 A. It is one of the things they look at, but

58:10 they look at other things as well.

58:11 Q. They also look at the -- at the -- for

58:12 example, the rate of adverse events with their filter

58:13 versus competitor filters. Fair?

58:14 A. Yes.

58:15 Q. And is the rate an important thing for them

58:16 to look at?

58:17 A. It's hard to look at it with a competitor

58:18 filter, because most of the time we do not have

58:19 competitor sales numbers. And so when we calculate

59:2 - 59:2

Wong, Natalie 10-18-2016 (00:00:01)

03_16_18 Combo final3.47

59:2 Q. Well, that's an analysis --

59:5 - 59:7

Wong, Natalie 10-18-2016 (00:00:07)

03_16_18 Combo final3.48

59:5 A. So I don't know if that rate is truly

59:6 accurate when we compare our rates to our competitor

59:7 rates.

59:8 - 59:25

Wong, Natalie 10-18-2016 (00:00:39)

03_16_18 Combo final3.49

59:8 Q. That's analysis Bard does. Right?

59:9 A. On a regular basis?

59:10 Q. Well, no, I'm asking you, that's an

59:11 analysis they do, right, they compare their rates to

59:12 competitor rates?

59:13 A. I -- when I worked on filters, yes, that's

59:14 something we did compare.

59:15 Q. And if that wasn't important, why would you

59:16 do that calculation?

59:17 A. We wanted to see how we compared to our

59:18 competitors.

59:19 Q. Yeah, and it's important to know how your

59:20 filter compares to your competitor filter, in terms

59:21 of adverse events and failure modes. Right?

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59:22 A. Yes.

59:23 Q. And Bard does that calculation because it's

59:24 an important piece of information?

59:25 A. It's an important -- yes, it is important.

62:25 - 63:4

Wong, Natalie 10-18-2016 (00:00:11)

03_16_18 Combo final3.50

62:25 Q. Ma'am, I'm handing you what has been marked
63:1 as Deposition Exhibit 537.

WONG 537.1

63:2 Is that -- is that an e-mail chain you've
63:3 seen before?

63:4 A. Yes.

63:5 - 63:7

Wong, Natalie 10-18-2016 (00:00:06)

03_16_18 Combo final3.51

63:5 Q. Is it an e-mail chain that was provided to
63:6 you by counsel in preparation for your deposition?

63:7 A. Yes.

63:12 - 63:15

Wong, Natalie 10-18-2016 (00:00:08)

03_16_18 Combo final3.52

63:12 So this is an e-mail from John Lehmann to
63:13 Robert Carr and Doug Uelmen, cc: Chris Ganser.
63:14 Correct?

WONG 537.4.1

63:15 A. Yes.

63:16 - 63:18

Wong, Natalie 10-18-2016 (00:00:07)

03_16_18 Combo final3.53

63:16 Q. Who are Robert Carr and Doug Uelmen?

clear

63:17 A. Robert Carr was in R&D. Doug Uelmen was
63:18 the VP of quality.

64:7 - 64:10

Wong, Natalie 10-18-2016 (00:00:06)

03_16_18 Combo final3.54

64:7 Q. And the subject
64:8 matter is "Draft data set for statistician." Did I
64:9 read that correctly?

WONG 537.4.2

64:10 A. Yes.

67:22 - 68:2

Wong, Natalie 10-18-2016 (00:00:23)

03_16_18 Combo final3.55

67:22 Q. So then if you look at the next
67:23 sentence up, I mean, the next e-mail up, excuse me,
67:24 one more up from that, there's an e-mail on May 18th
67:25 of 2004 from Doug Uelmen to you, that says, "Dear
68:1 Natalie: The data."

WONG 537.3.2

WONG 537.3.3

68:2 A. Okay.

68:5 - 68:7

Wong, Natalie 10-18-2016 (00:00:02)

03_16_18 Combo final3.56

68:5 Q. And that was sent to you on May 18th of
68:6 2004?

clear

68:7 A. Yes.

68:11 - 68:14

Wong, Natalie 10-18-2016 (00:00:05)

03_16_18 Combo final3.57

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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68:11 Q. What was the purpose of sending you this
68:12 data?

68:13 A. He wanted me to do a quick analysis of the
68:14 data.

68:25 - 69:1

Wong, Natalie 10-18-2016 (00:00:02)

03_16_18 Combo final3.58

68:25 Q. And so you did an analysis. Correct?

69:1 A. Yes.

69:17 - 70:9

Wong, Natalie 10-18-2016 (00:00:38)

03_16_18 Combo final3.59

69:17 Q. You were going to

69:18 calculate -- you were going to calculate the IVC --

69:19 the IVC filter-related deaths with the Bard filter

69:20 and also with the competitors?

69:21 A. Yes.

69:22 Q. Okay. And your ultimate conclusion there,

69:23 on May 20th of 2004 -- that's an e-mail from you.

69:24 Correct?

69:25 A. Yes.

70:1 Q. And that's to Doug Uelmen. Correct?

70:2 A. Yes.

70:3 Q. And you said, "Doug, I've evaluated the

70:4 data comparing Recovery with the other products.

70:5 These results included quarter 2, 2004." Right?

70:6 A. Yes.

70:7 Q. And you say, "Based on the limited amount

70:8 of data, the following can be concluded." Right?

70:9 A. Yes.

70:10 - 70:17

Wong, Natalie 10-18-2016 (00:00:23)

03_16_18 Combo final3.60

70:10 Q. And the first one is, there's not a

70:11 significant difference between the Recovery and the

70:12 TrapEase, OptEase, Greenfield, and VenaTech. Fair?

70:13 A. Yes.

70:14 Q. And that's -- but -- but you're careful to

70:15 say "at a 95 percent confidence interval." Right?

70:16 A. Well, I remember I was careful, because I

70:17 said that there was a limited amount of data.

71:7 - 72:1

Wong, Natalie 10-18-2016 (00:00:47)

03_16_18 Combo final3.61

71:7 Q. as for number two,

71:8 though, you say, "At a 95 percent confidence

71:9 interval, there is a significant difference between

71:10 Recovery and G|nther Tulip, Birds Nest, and SNF."

WONG 537.3.4

WONG 537.2.3

clear

WONG 537.2.2

WONG 537.2.1

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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71:11 A. Yes.

71:12 Q. Right?

71:13 And that significant difference is the

71:14 Recovery has a higher risk of death associated with

71:15 it than those other filters. Right?

71:16 A. I think the math showed there was a

71:17 difference, yes.

71:18 Q. It was higher. Right?

71:19 A. I believe so. I have to look at the data

71:20 again, yeah.

71:21 Q. Okay. And the Glnther Tulip and the Birds

71:22 Nest, those are competitors of the Recovery. Right?

71:23 A. Yes.

71:24 Q. And the SNF is actually the predicate

71:25 device for the Recovery. Right?

72:1 A. Yes.

72:6 - 72:12

Wong, Natalie 10-18-2016 (00:00:16)

72:6 Q. The Recovery was not statistically

72:7 equivalent to the SNF, based on your calculations

72:8 with regard to deaths associated with the filter.

72:9 Right?

72:10 A. Yes.

72:11 Q. Yes, I'm correct?

72:12 A. Yes.

73:10 - 73:24

Wong, Natalie 10-18-2016 (00:00:41)

73:10 Q. And my question is, based on your

73:11 calculations here, would it be inaccurate to say that

73:12 the Recovery filter is better than the SNF filter.

73:13 Fair?

73:14 A. Yes.

73:15 Q. And it would be inaccurate to say it's --

73:16 it's the equivalent of the SNF filter?

73:17 A. I don't know, no.

73:18 Yes, they are not equivalent.

73:19 Q. The SNF --

73:20 A. If that was your question.

73:21 Q. Yeah, the -- the -- the Recovery filter is

73:22 worse than the SNF, based on your calculations with

73:23 regard to filter deaths. Fair?

73:24 A. Based on the limited data, yes.

clear

03_16_18 Combo final3.62

03_16_18 Combo final3.63

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73:25 - 74:4

Wong, Natalie 10-18-2016 (00:00:11)

03_16_18 Combo final3.64

73:25 Q. And that was the data you had

74:1 available. Right?

74:2 A. Right. And, normally, I wouldn't do this

74:3 analysis without more datapoints, which is why I said

74:4 "limited data," because I wasn't very confident.

77:7 - 77:8

Wong, Natalie 10-18-2016 (00:00:02)

03_16_18 Combo final3.65

77:7 Q. And is that something that you think

77:8 physicians need to know?

77:12 - 77:20

Wong, Natalie 10-18-2016 (00:00:26)

03_16_18 Combo final3.66

77:12 A. Yes.

77:13 Q. And is that something you're aware of ever

77:14 being provided to physicians?

77:15 A. That I don't know.

77:16 Q. And, based on your calculations, let's look

77:17 at page -- let's look at this chart that you did, the

77:18 Product Statistical Summary chart. Do you see where

77:19 I'm looking?

77:20 A. Yes.

WONG 537.7

78:1 - 78:21

Wong, Natalie 10-18-2016 (00:00:54)

03_16_18 Combo final3.67

78:1 Q. And despite not finding statistical

78:2 significance with regards to any of the other

78:3 filters, none of the other filters had even half of

78:4 the -- the adverse -- the death average that the

78:5 Recovery did. Fair?

78:6 A. Yes. Based on the data provided.

78:7 Q. And the Recovery had a higher average of

78:8 deaths associated with those filters than any of the

78:9 other filters that you did the calculation for?

78:10 A. Yes.

78:11 Q. At least twice as much?

78:12 A. Yes.

78:13 Q. And with regard to the SNF, the average was

78:14 literally zero. Right?

78:15 A. Yes.

78:16 Q. And that was the predicate device for the

78:17 Recovery?

78:18 A. Yes.

78:19 Q. And the Recovery is -- the Recovery is

78:20 certainly not equivalent to or better than the SNF,

WONG 537.7.4

WONG 537.7.5

clear

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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78:23 - 78:24	<p>78:21 fair, in this issue?</p> <p>Wong, Natalie 10-18-2016 (00:00:05)</p> <p>78:23 THE WITNESS: Just based on these numbers,</p> <p>78:24 no, they're not equivalent.</p>	03_16_18 Combo final3.68
79:2 - 79:9	<p>Wong, Natalie 10-18-2016 (00:00:24)</p> <p>79:2 Q. And what was this chart used for?</p> <p>79:3 A. I don't know what was -- what it was used</p> <p>79:4 for. I summarize what I was looking at to provide to</p> <p>79:5 Doug, but it --</p> <p>79:6 Q. And it was for -- oh, sorry, go ahead.</p> <p>79:7 A. You know, the number of samples for this</p> <p>79:8 data analysis was really low. Typically, we want 30</p> <p>79:9 samples to do --</p>	03_16_18 Combo final3.69
79:25 - 80:4	<p>Wong, Natalie 10-18-2016 (00:00:16)</p> <p>79:25 Q. But, just by your calculation, it</p> <p>80:1 wasn't statistically significant, within a 95 percent</p> <p>80:2 confidence interval?</p> <p>80:3 A. To calculate statistical significance,</p> <p>80:4 usually you need around 30 samples.</p>	03_16_18 Combo final3.70
80:13 - 80:23	<p>Wong, Natalie 10-18-2016 (00:00:31)</p> <p>80:13 Q. My question is, you're just saying here --</p> <p>80:14 you're saying, at a 95 percent confidence interval,</p> <p>80:15 there is not a significant difference between the</p> <p>80:16 Recovery and TrapEase, OptEase, Greenfield, and</p> <p>80:17 VenaTech, what you're saying there is you didn't find</p> <p>80:18 a statistically significant difference. Fair?</p> <p>80:19 A. Based on the limited data provided, yes.</p> <p>80:20 Q. But the rates -- the rate -- the average</p> <p>80:21 rate of death actually was higher with the Recovery</p> <p>80:22 than those other filters?</p> <p>80:23 A. Yes.</p>	03_16_18 Combo final3.71 WONG 537.7.4
83:1 - 83:4	<p>Wong, Natalie 10-18-2016 (00:00:14)</p> <p>83:1 Q. To calculate the percent failure?</p> <p>83:2 A. I couldn't -- yeah, I couldn't predict the</p> <p>83:3 percent failure, because I think I needed more</p> <p>83:4 datapoints to help with analysis of it.</p>	03_16_18 Combo final3.72 clear
84:23 - 85:15	<p>Wong, Natalie 10-18-2016 (00:00:51)</p> <p>84:23 Q. All right. Ma'am, you've been handed</p> <p>84:24 what's been marked as Deposi -- Deposition Exhibit</p> <p>84:25 538.</p>	03_16_18 Combo final3.73 WONG 538.1

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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	85:1 Are you familiar with what an HHE is?	
	85:2 A. Yes.	
	85:3 Q. And what is an HHE?	WONG 538.1.1
	85:4 A. It's written by our medical director to	
	85:5 talk about, you know, it's usually asked during an	
	85:6 investigation to do a risk-benefit analysis on the	
	85:7 complaints that we receive.	
	85:8 Q. And this is -- and "HHE" stands for Health	
	85:9 Hazard Evaluation; is that right?	
	85:10 A. Yes.	
	85:11 Q. And who is -- and this is from David	WONG 538.1.2
	85:12 Ciavarella to Doug Uelmen. Who is David Ciavarella?	
	85:13 A. I think he was our medical director.	
	85:14 Q. And this is on December 17th of 2004?	
	85:15 A. Yes, that's what the document says.	
87:22 - 87:23	Wong, Natalie 10-18-2016 (00:00:03)	03_16_18 Combo final3.75
	87:22 Q. My question is, do you think it would be	clear
	87:23 important for physicians to have this information?	
87:25 - 88:1	Wong, Natalie 10-18-2016 (00:00:02)	03_16_18 Combo final3.76
	87:25 THE WITNESS: Yes.	
	88:1 BY MR. DEGREEFF:	
88:16 - 89:3	Wong, Natalie 10-18-2016 (00:00:28)	03_16_18 Combo final3.77
	88:16 Q. Are you familiar at all with the IFU for	
	88:17 Bard filters?	
	88:18 A. I've read it before.	
	88:19 Q. Have you ever seen in the IFU where there	
	88:20 was any statement about an increased risk of death	
	88:21 with the -- with a Bard filter versus competitors?	
	88:22 A. We don't talk about competitors in our	
	88:23 IFUs, no.	
	88:24 Q. Okay. So, no where -- no where in the IFU	
	88:25 would there -- would there ever be a statement about	
	89:1 an increased risk with Bard filters versus other	
	89:2 filters?	
	89:3 A. No.	
100:5 - 100:6	Wong, Natalie 10-18-2016 (00:00:02)	03_16_18 Combo final3.78
	100:5 Q. 539, sorry. Do you have that?	WONG 539.1
	100:6 A. Yes.	
100:10 - 100:12	Wong, Natalie 10-18-2016 (00:00:10)	03_16_18 Combo final3.79
	100:10 Q. What is a remedial action plan?	WONG 539.1.1

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106:23 - 107:2	<p>100:11 A. It's -- it's an investigation on root cause</p> <p>100:12 and what actions we're doing about it.</p> <p>Wong, Natalie 10-18-2016 (00:00:11)</p> <p>106:23 Q. it was never</p> <p>106:24 stated in the IFU that there was an increased risk of</p> <p>106:25 migration, or death, or fracture or anything else</p> <p>107:1 with the Bard filters versus other filters?</p> <p>107:2 A. Not that I know of.</p>	<p>03_16_18 Combo final3.80</p> <p>clear</p>
109:24 - 110:13	<p>Wong, Natalie 10-18-2016 (00:00:41)</p> <p>109:24 Q. All right, ma'am, I'm handing you what's</p> <p>109:25 been marked as Deposition Exhibit 540. And this is</p> <p>110:1 titled -- this is a June 20th, 2006 "Recovery</p> <p>110:2 Fracture and Migration Complaint Update." Correct?</p> <p>110:3 A. Yes.</p> <p>110:4 Q. And you were on the IVC team at this point.</p> <p>110:5 Fair?</p> <p>110:6 A. Yes.</p> <p>110:7 Q. Is this something that you would have</p> <p>110:8 prepared?</p> <p>110:9 A. Yes. Let me flip through real quick. Yes.</p> <p>110:10 Q. And let's look at -- if you would, let's</p> <p>110:11 start with page 4, I guess page 4 in the lower</p> <p>110:12 right-hand corner?</p> <p>110:13 A. Okay.</p>	<p>03_16_18 Combo final3.81</p> <p>WONG 540.1</p> <p>WONG 540.1.1</p> <p>clear</p> <p>WONG 540.4.1</p>
110:18 - 111:25	<p>Wong, Natalie 10-18-2016 (00:01:38)</p> <p>110:18 Q. And here we are, a year, year and a half</p> <p>110:19 later and -- and Bard is still looking at MAUDE data?</p> <p>110:20 A. Yes.</p> <p>110:21 Q. And on the left hand we've got products</p> <p>110:22 listed on this chart right and it's the Recovery and</p> <p>110:23 SNF which are Bard products. Correct?</p> <p>110:24 A. Yes.</p> <p>110:25 Q. And then one, two, three, four, five, six,</p> <p>111:1 six competitors. Right?</p> <p>111:2 A. Yes.</p> <p>111:3 Q. And on the other side, the far right-hand</p> <p>111:4 side, we've got the rate, what does -- what does rate</p> <p>111:5 mean?</p> <p>111:6 A. I think it's the filter fracture rate.</p> <p>111:7 Q. And the filter fracture rate for the</p>	<p>03_16_18 Combo final3.82</p> <p>WONG 540.4.2</p> <p>WONG 540.4.3</p> <p>WONG 540.4.4</p>

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	111:8 Recovery is .1915 percent. Correct?	
	111:9 A. Yes.	
	111:10 Q. And none of the other filters on the list	WONG 540.4.5
	111:11 are even half as high as the Recovery fracture rate.	
	111:12 Fair?	
	111:13 A. Bird Nest is almost half as high.	
	111:14 Q. But it's not half as high, is it?	
	111:15 A. Barely. Yes, it's not half as high.	WONG 540.4.7
	111:16 Q. And so -- and if we look at SNF, SNF had	
	111:17 three filter fractures in 84,520 units sold. Right?	
	111:18 A. Yes.	
	111:19 Q. Versus the Recovery had 66 fractures in	
	111:20 only 34,467 units sold. Right?	
	111:21 A. Yes.	
	111:22 Q. Fair to say that the Recovery is not	
	111:23 equivalent to the SNF with regards to filter	
	111:24 fracture?	
	111:25 A. Yes.	
112:16 - 112:22	Wong, Natalie 10-18-2016 (00:00:18)	03_16_18 Combo final3.83
	112:16 Q. It fractures less than the RNF? It	clear
	112:17 fractures at a lower rate than the RNF?	
	112:18 A. The rate is lower, yes.	
	112:19 Q. And, in fact, all of the competitors'	
	112:20 fracture, based on this calculation, at a lower rate	
	112:21 than the Recovery also?	
	112:22 A. Based on the MAUDE data, yes.	
114:10 - 114:15	Wong, Natalie 10-18-2016 (00:00:25)	03_16_18 Combo final3.84
	114:10 Q. is it consistent with the	
	114:11 statement in there that there's an increased risk of	
	114:12 fracture with the Recovery versus the other filters?	
	114:13 A. Yes.	
	114:14 Q. All right. Look at page 18, if you would.	WONG 540.18
	114:15 And is this a -- what is this document?	
114:18 - 114:20	Wong, Natalie 10-18-2016 (00:00:08)	03_16_18 Combo final3.85
	114:18 A. Okay. So this table is comparing the	
	114:19 complaints that we have received and comparing it	
	114:20 against the DFMEA rankings.	
115:12 - 115:15	Wong, Natalie 10-18-2016 (00:00:14)	03_16_18 Combo final3.86
	115:12 Q. My question is this is a DFMEA analysis,	
	115:13 right, it's a ranking of the injuries?	

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	115:14 A. It's a subset of the DFMEA, it's comparing 115:15 what our complaint rate is compared to our DFMEA.	clear
116:2 - 116:11	Wong, Natalie 10-18-2016 (00:00:23) 116:2 Q. This is being done 116:3 in 2006. Right? 116:4 A. Yes. 116:5 Q. And the Recovery filter is not even on the 116:6 market in 2006; is that correct? 116:7 A. Yes. I believe so. 116:8 Q. So why -- why are you still doing a DFMEA 116:9 analysis of a filter that's not even on the market? 116:10 A. Because I think we're still concerned about 116:11 complaints that are coming in.	03_16_18 Combo final3.87
120:4 - 120:12	Wong, Natalie 10-18-2016 (00:00:27) 120:4 Q. was it ever conveyed to 120:5 physicians and patients that an R00 -- that a risk 120:6 analysis had been performed by Bard and that -- that 120:7 the fracture risk rate was found to be undesirable? 120:8 A. I don't know. 120:9 Q. Are you aware of that ever happening? 120:10 A. I don't believe so. 120:11 Q. Is that something you think that physicians 120:12 and patients need to know about?	03_16_18 Combo final3.88
120:14 - 120:20	Wong, Natalie 10-18-2016 (00:00:16) 120:14 THE WITNESS: No. 120:15 BY MR. DEGREEFF: 120:16 Q. You don't think it's important that an 120:17 internal Bard analysis finding an undesirable risk 120:18 assessment ranking for -- for fracture with regard to 120:19 the Recovery is something that physicians and 120:20 patients need to know about?	03_16_18 Combo final3.89
120:22 - 120:22	Wong, Natalie 10-18-2016 (00:00:06) 120:22 THE WITNESS: I don't know.	03_16_18 Combo final3.90
121:15 - 121:24	Wong, Natalie 10-18-2016 (00:00:31) 121:15 THE WITNESS: I think physicians should 121:16 know. 121:17 BY MR. DEGREEFF: 121:18 Q. But not patients? 121:19 A. I think it's -- the physician should relay 121:20 to the patients about the risk and benefit of a	03_16_18 Combo final3.91

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	121:21 device.	
	121:22 Q. And they can't do that unless they know	
	121:23 about it. Right?	
	121:24 A. Right.	
122:9 - 122:22	Wong, Natalie 10-18-2016 (00:00:31)	03_16_18 Combo final3.92
	122:9 Q. I've handed you what's been marked as	
	122:10 Deposition Exhibit 541. Does that -- have you got it	WONG 541.1
	122:11 in front of you?	
	122:12 A. Yes.	
	122:13 Q. And this is, the cover page to this is an	
	122:14 e-mail from you to Gin Schulz providing the updated	WONG 541.1.1
	122:15 RNF draft report; is that right?	
	122:16 A. Yes.	
	122:17 Q. And that was on August 4th of 2006?	
	122:18 A. Yes.	
	122:19 Q. And you say, "Gin, attached is the updated	WONG 541.1.2
	122:20 RNF fracture report with the comments from today's	
	122:21 meeting." Right?	
	122:22 A. Yes.	
129:1 - 129:9	Wong, Natalie 10-18-2016 (00:00:23)	03_16_18 Combo final3.93
	129:1 Q. So if this is not an	clear
	129:2 acceptable rate then why is it being used -- why is	
	129:3 it included here as -- why is it relevant?	
	129:4 A. It's a comparison.	
	129:5 Q. Why compare something you don't think is	
	129:6 acceptable?	
	129:7 A. It was accepted by industry for the SIR	
	129:8 guidelines. We were just comparing our numbers to	
	129:9 what those rates were in that article.	
129:25 - 130:12	Wong, Natalie 10-18-2016 (00:00:35)	03_16_18 Combo final3.94
	129:25 Q. Looking down to the second bullet	
	130:1 point it says, "RNF had 115 fractures out of 34,315	WONG 541.12.1
	130:2 sales, for a rate of .34 percent." Correct?	
	130:3 A. Yes.	
	130:4 Q. And then the third -- the fourth bullet	
	130:5 point down says, that the SNF had three fractures	WONG 541.12.2
	130:6 with unit sales of 22,000, for a fracture rate of .01	
	130:7 percent. Correct?	
	130:8 A. Yes.	
	130:9 Q. So, again, the RNF was significantly higher	

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130:17 - 130:18	<p>130:10 than the SNF in fracture rate. Fair?</p> <p>130:11 A. It's higher. I don't know if it's</p> <p>130:12 significantly higher.</p> <p>Wong, Natalie 10-18-2016 (00:00:02)</p> <p>130:17 Q. It's 33 times higher?</p> <p>130:18 A. Yeah.</p>	03_16_18 Combo final3.95
130:19 - 130:19	<p>Wong, Natalie 10-18-2016 (00:00:01)</p> <p>130:19 Q. Is that significant?</p>	03_16_18 Combo final3.96
130:21 - 130:22	<p>Wong, Natalie 10-18-2016 (00:00:06)</p> <p>130:21 THE WITNESS: It's higher. I don't know if</p> <p>130:22 it's statistically significant. It is higher.</p>	03_16_18 Combo final3.97
130:24 - 131:2	<p>Wong, Natalie 10-18-2016 (00:00:08)</p> <p>130:24 Q. So, based on this, it's not accurate</p> <p>130:25 to say that the SNF and the RNF are similar in</p> <p>131:1 fracture resistance. Fair?</p> <p>131:2 A. Yes.</p>	03_16_18 Combo final3.98 clear
131:7 - 131:12	<p>Wong, Natalie 10-18-2016 (00:00:18)</p> <p>131:7 It's not accurate to say that the RNF was</p> <p>131:8 an improvement on the SNF with regard to fracture.</p> <p>131:9 Fair?</p> <p>131:10 A. I don't know. SNF is a permanent filter,</p> <p>131:11 Recovery's retrievable. So the true rate of fracture</p> <p>131:12 on a SNF, I don't know what that is.</p>	03_16_18 Combo final3.99
131:19 - 131:22	<p>Wong, Natalie 10-18-2016 (00:00:09)</p> <p>131:19 Q. Based on this data, it's not</p> <p>131:20 accurate to say that the RNF is an improvement on the</p> <p>131:21 SNF with regard to fracture. Fair?</p> <p>131:22 A. It is not an improvement, no.</p>	03_16_18 Combo final3.100
135:3 - 135:13	<p>Wong, Natalie 10-18-2016 (00:00:41)</p> <p>135:3 Q. What is being marked as Deposition Exhibit</p> <p>135:4 542.</p> <p>135:5 A. Thank you.</p> <p>135:6 Q. And this is an e-mail exchange between you</p> <p>135:7 and Sandy Kerns, on December 2nd of 2009. Correct?</p> <p>135:8 A. Yes. I was in field assurance at the time.</p> <p>135:9 Q. And who is Sandy Kerns?</p> <p>135:10 A. She's a field assurance coordinator.</p> <p>135:11 Q. Okay. And she e-mails you and says "How</p> <p>135:12 many filters fractures were in November?" Right?</p> <p>135:13 A. Yes.</p>	03_16_18 Combo final3.101 WONG 542.1 WONG 542.1.1 WONG 542.2

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135:18 - 136:13	Wong, Natalie 10-18-2016 (00:00:55) 135:18 Q. And your -- your response was "19." 135:19 Correct? 135:20 A. Yes. 135:21 Q. That means there was 19 filter fractures 135:22 reported in November of 2009 -- 135:23 A. Yes. 135:24 Q. -- is that right? 135:25 Is 19 a lot of fractures for a month? 136:1 A. I don't remember. It sounds like a lot. 136:2 Q. Well, if there was 19 reported for one 136:3 month, over the course of a year, that extrapolates 136:4 to 221. Right? 136:5 A. Yeah, around that. But -- 136:6 Q. Is that a lot? Would that be a lot of 136:7 filter fractures in a year? 136:8 A. Yeah. It's -- it sounds unusually high for 136:9 November, 19. 136:10 Q. Well, you're -- it sounds like you're 136:11 right, because Sandy's response is "youch." Correct? 136:12 A. Uh-huh. Yup. 136:13 Q. And what do you think she meant by that?	03_16_18 Combo final3,102 WONG 542.1.3 clear WONG 542.1.4
136:15 - 136:15	Wong, Natalie 10-18-2016 (00:00:02) 136:15 THE WITNESS: That it's a lot for a month.	03_16_18 Combo final3,103
136:17 - 137:4	Wong, Natalie 10-18-2016 (00:00:37) 136:17 Q. what was done within Bard about 136:18 the fact that there was 19 filter fractures reported 136:19 in a single month? 136:20 A. I don't know. I mean, I would have to look 136:21 at what those 19 were. I don't know -- I don't 136:22 recall, from 2009, if there was a trend. 136:23 Q. Okay. If you're -- if Bard is seeing 136:24 something like 19 filter fractures in a single month, 136:25 is -- how would they let physicians or patients know 137:1 about this? 137:2 A. They wouldn't let physicians or patients 137:3 know yet. I think we would look at the 19 and 137:4 understand why there were 19.	03_16_18 Combo final3,104 clear
138:12 - 138:22	Wong, Natalie 10-18-2016 (00:00:23) 138:12 Q. What we do know is that there was 19	03_16_18 Combo final3,105

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	138:13 filter fractures in November of 2009. Right?	
	138:14 A. Yes.	
	138:15 Q. And that's -- and we also know there's not	
	138:16 an internal system within Bard to make physicians and	
	138:17 patients aware of that -- of that kind of large	
	138:18 number of fractures?	
	138:19 A. No.	
	138:20 Q. I think we're agreeing. You're saying yes,	
	138:21 there is no internal process. Correct?	
	138:22 A. Yes, there is no internal process.	
139:15 - 139:25	Wong, Natalie 10-18-2016 (00:00:20)	03_16_18 Combo final3.106
	139:15 Q. We would consider -- would you consider	
	139:16 this a spike in filter fractures?	
	139:17 A. I would have to look at the trend.	
	139:18 Q. Sandy Kerns seems to think it's a spike,	
	139:19 doesn't she, when she says "youch"?	
	139:20 A. Yeah, I think it would be a spike.	
	139:21 Q. And didn't we talk earlier about the fact	
	139:22 that that was something that would be important to	
	139:23 the trending and tracking?	
	139:24 A. Yes, and these would have been tracked and	
	139:25 trended.	
140:5 - 140:10	Wong, Natalie 10-18-2016 (00:00:12)	03_16_18 Combo final3.107
	140:5 Q. At what point in the process would -- would	
	140:6 physicians and patients be made aware of a spike in	
	140:7 fractures?	
	140:8 A. If it was a true spike, and we couldn't	
	140:9 explain it, it would go down the investigation	
	140:10 pathway.	
141:17 - 142:6	Wong, Natalie 10-18-2016 (00:00:46)	03_16_18 Combo final3.108
	141:17 Q. And do you have 543 in front of you?	WONG 543.1
	141:18 A. Yes.	
	141:19 Q. And this is an e-mail from you to several	WONG 543.1.1
	141:20 people attaching a presentation on caudal migration.	
	141:21 Correct?	
	141:22 A. Yes, for G2.	
	141:23 Q. Yeah, excuse me, for G2. And it's dated	
	141:24 March 2nd of 2006?	
	141:25 A. Yes.	
	142:1 Q. And was this something you prepared?	

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	142:2 A. Yes.	
	142:3 Q. And you were actually the lead investigator	
	142:4 on the G2 caudal migration failure investigations	
	142:5 report. Right?	
	142:6 A. Yes. With the support of my team.	
145:19 - 146:20	Wong, Natalie 10-18-2016 (00:01:40)	03_16_18 Combo final3.109
	145:19 Q. And now look at the next page, if you	
	145:20 would. Here we've got "G2 Compared to SNF and RNF,"	WONG 543.8
	145:21 is the heading. Right?	
	145:22 A. Yes.	
	145:23 Q. It says as of 2/28/06, SNF had zero caudal	WONG 543.8.1
	145:24 migrations reported out of 34,000 sales. Right?	
	145:25 A. Yes.	WONG 543.8.2
	146:1 Q. And the RNF had three caudal migrations	
	146:2 reported out of 25,000 sales, right, for a caudal	
	146:3 migration rate of .01?	
	146:4 A. Yes.	
	146:5 Q. And do we know what the rate for the SNF	
	146:6 was? I think if you look on page --	
	146:7 A. SNF is zero.	clear
	146:8 Q. Or, excuse me, do we know what the rate for	
	146:9 the G2 was?	
	146:10 A. .15 percent.	
	146:11 Q. And that was -- that was 13 migrations in	
	146:12 only 8,900 sold?	
	146:13 A. 13 migrations in 8,924 sold, yes.	
	146:14 Q. And fair to say that the Recovery is more	
	146:15 resistant to caudal migration than the G2?	
	146:16 A. Yeah, I don't think we had that many	
	146:17 reports of caudal migration with Recovery.	
	146:18 Q. And the SNF is, given that it had zero	
	146:19 caudal migrations reported, it's certainly more	
	146:20 resistant to caudal migration than the G2. Correct?	
146:22 - 146:23	Wong, Natalie 10-18-2016 (00:00:03)	03_16_18 Combo final3.110
	146:22 THE WITNESS: Yes, there were no caudal	
	146:23 migrations of the SNF.	
147:22 - 148:10	Wong, Natalie 10-18-2016 (00:00:46)	03_16_18 Combo final3.111
	147:22 Based on the actual real-life data that was	
	147:23 available versus hypothetical world, the -- the G2	
	147:24 was less -- the -- excuse me, the SNF was better than	

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	147:25 the G2 with regards to caudal migration?	
	148:1 MS. DALY: He's talking about based on your	
	148:2 data here.	
	148:3 THE WITNESS: That SNF -- sorry, SNF is	
	148:4 better than G2 on caudal migration, yes.	
	148:5 BY MR. DEGREEFF:	
	148:6 Q. And it would be -- based on the data	
	148:7 that's -- the available data that's in this	
	148:8 spreadsheet, it would be inaccurate to say that the	
	148:9 G2 was more stable than the -- than the RNF.	
	148:10 Correct?	
148:12 - 148:12	Wong, Natalie 10-18-2016 (00:00:05)	03_16_18 Combo final3.112
	148:12 THE WITNESS: Yes.	
151:19 - 152:9	Wong, Natalie 10-18-2016 (00:00:50)	03_16_18 Combo final3.113
	151:19 Q. Okay. Look at the next page, if you would.	WONG 543.16
	151:20 This is the caudal severity description. And I'm	
	151:21 looking at type III and type IV. Caudal migration	WONG 543.16.2
	151:22 can be -- can result in a reintervention to remove	
	151:23 the filter. Right?	
	151:24 A. Yes, for -- for the type III.	
	151:25 Q. And, yeah, and caudal migration can result	
	152:1 in the need to repair damage to a patient's anatomy?	WONG 543.16.3
	152:2 A. Yes.	
	152:3 Q. And caudal migration can result in patient	WONG 543.16.4
	152:4 injury?	
	152:5 A. Yes.	
	152:6 Q. And caudal migration can result in a filter	WONG 543.16.6
	152:7 no longer providing its primary function of -- of	
	152:8 protection from pulmonary embolism?	
	152:9 A. Yes.	
152:25 - 156:3	Wong, Natalie 10-18-2016 (00:04:22)	03_16_18 Combo final3.114
	152:25 And caudal migration can also result in	WONG 543.16.7
	153:1 excessive tilt; is that right?	
	153:2 A. Yes.	
	153:3 Q. And it can also result in an arm and leg --	
	153:4 an arm or leg in a side branch of the vena cava?	
	153:5 A. Yes.	
	153:6 Q. And caudal migration can also result in	
	153:7 iliac or renal confluence?	
	153:8 A. I think here it's saying it could be in --	

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153:9 it could migrate to the iliac renal confluence.

153:10 Q. Yeah, you're right, correct. And caudal

153:11 migration can also result in perforation?

153:12 A. Yes.

153:13 Q. And caudal migration can result in -- in

153:14 death, correct, according to the type IV?

WONG 543.16.8

153:15 A. Yes.

153:16 Q. And life-threatening injury?

WONG 543.16.9

153:17 A. Yes.

153:18 Q. All right. Let's look at the -- there's

clear

153:19 a -- there's a -- a later one that says "G2 caudal

153:20 threshold."

153:21 A. There's two of them, which one?

153:22 Q. The one -- the DFMEA.

153:23 A. The first one?

WONG 543.20

153:24 Q. Yeah.

153:25 A. Okay.

154:1 Q. And is this a DFMEA, I guess it's kind of

154:2 the -- the presentation of the DFMEA?

154:3 A. Hold on, let me look at this real quick.

clear

154:4 So this is not the DFMEA. This is comparing our

154:5 complaints and our complaint rate to the typing that

154:6 we reviewed earlier to the ranking that's within the

154:7 DFMEA.

WONG 543.20.1

154:8 Q. Okay. Well, the -- the ultimate ranking on

154:9 this, and you -- it's in a red box, pointing to quad

154:10 level states, that for type III and type IV the quad

154:11 level was, "Unacceptable risk per FMEA, type III

154:12 above threshold." Correct?

154:13 A. Yes, that's what it says.

154:14 Q. And -- and what does that mean?

154:15 A. So it's saying, with the severity that's

154:16 been established with our complaint rate, that our --

154:17 that for type III, it's above the threshold of .05

154:18 percent.

154:19 Q. And so if you look down in the -- in the

154:20 left-hand corner, it -- if you look at quad versus

WONG 543.20.3

154:21 detection ranking, B says, Quad 3 or 4, which we've

154:22 got, right? It's a Quad 3 or 4, isn't it, type III

154:23 or type --

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154:24 A. Sorry, yes.

154:25 Q. And then it says "with detection of three

155:1 to five" -- and we've got detection of five.

155:2 Correct?

155:3 A. Yes.

155:4 Q. -- "requires recommended action prior to

155:5 product release." Right?

155:6 A. Yes.

155:7 Q. And in this case, the G2 has already been

155:8 released. Right?

155:9 A. Right.

155:10 Q. And so what was done to inform patients and

155:11 physicians that additional recommend -- that

155:12 additional actions were needed, and that there was an

155:13 unacceptable risk?

155:14 A. There was no communication.

155:15 Q. Why not?

155:16 A. Because I think when we started

155:17 investigating this, there were 13 and we're still

155:18 investigating why we haven't gone through the whole

155:19 investigation process yet.

155:20 Q. But you've got a -- you've got a product

155:21 that's already on the market. Right?

155:22 A. Yes.

155:23 Q. And you've got an unacceptable risk per

155:24 Bard's internal FMEA analysis. Right?

155:25 A. Through this analysis, yes.

156:1 Q. And you've got -- and -- and that requires

156:2 action to be taken by Bard. Correct?

156:3 A. Yes.

156:19 - 157:3

Wong, Natalie 10-18-2016 (00:00:32)

156:19 Q. You've had 13 complaints in 8,000 sales

156:20 with this -- with this G2 filter of caudal migration,

156:21 and only three in over 30,000 with the RNF. Right?

156:22 A. Right.

156:23 Q. So that's -- that's trending in a bad

156:24 direction for -- with regard to caudal migration.

156:25 Fair?

157:1 A. Yes, but it's also limited data, because

157:2 when I put the summary together, I think we're four

clear

03_16_18 Combo final3.115

WONG 543.20.4

clear

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157:6 - 157:15	<p>157:3 months.</p> <p>Wong, Natalie 10-18-2016 (00:00:36)</p> <p>157:6 So the number of complaints that you've got</p> <p>157:7 at the time you do this FMEA analysis is 13. Right?</p> <p>157:8 A. Right.</p> <p>157:9 Q. And eight of those are type III. Correct?</p> <p>157:10 A. Yes.</p> <p>157:11 Q. And type III includes that "the filter is</p> <p>157:12 no longer providing primary function of protection</p> <p>157:13 from PE," right? Or a perforation or an injury.</p> <p>157:14 Correct?</p> <p>157:15 A. Yes.</p>	<p>03_16_18 Combo final3.116</p> <p>WONG 543.20.5</p>
157:16 - 157:21	<p>Wong, Natalie 10-18-2016 (00:00:19)</p> <p>157:16 Q. So this is -- this is a relatively</p> <p>157:17 significant typing, right, I mean, type III is the</p> <p>157:18 second -- second to highest?</p> <p>157:19 A. If the complaint came in and if -- and</p> <p>157:20 if -- it was any one of those three, being</p> <p>157:21 conservative, we'd marked it as a type III.</p>	<p>03_16_18 Combo final3.117</p> <p>clear</p>
157:22 - 159:4	<p>Wong, Natalie 10-18-2016 (00:01:25)</p> <p>157:22 Q. any one of those things,</p> <p>157:23 the filter not being effective, injury or</p> <p>157:24 perforation, none of those are good things. Right?</p> <p>157:25 A. No.</p> <p>158:1 Q. I think you're agreeing with me. Am I</p> <p>158:2 correct?</p> <p>158:3 A. Yes, none of them are good things.</p> <p>158:4 Q. Okay. And eight of the 13 caudal migration</p> <p>158:5 reports had those issues?</p> <p>158:6 A. Had one or more of those issues.</p> <p>158:7 Q. So even under Bard's own analysis,</p> <p>158:8 the G2 caudal migration risk was unacceptable as of</p> <p>158:9 this date?</p> <p>158:10 A. Unacceptable -- unacceptable per the FMEA.</p> <p>158:11 Q. Which is Bard's internal analysis.</p> <p>158:12 Correct?</p> <p>158:13 A. Yes.</p> <p>158:14 Q. Now, looking at the next page, this is the</p> <p>158:15 R002 ranking. Correct?</p> <p>158:16 A. Yes.</p>	<p>03_16_18 Combo final3.118</p>

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	158:17 Q. And it ranks type III migrations as a	WONG 543.21.2
	158:18 potential severity of critical. Right?	
	158:19 A. Yes.	
	158:20 Q. And critical means, "A failure that can	
	158:21 contribute to death, severe injury, permanent	
	158:22 significant disability or severe occupational illness	
	158:23 in a patient or device user."	
	158:24 Did I read that correctly?	
	158:25 A. Yes.	
	159:1 Q. And eight of the 13 G2 caudal complaints	clear
	159:2 that Bard had at this time fit into that critical	
	159:3 category. Right?	
	159:4 A. Yes.	
159:12 - 159:16	Wong, Natalie 10-18-2016 (00:00:15)	03_16_18 Combo final3.119
	159:12 Q. Isn't that, the fact that eight of the 13	
	159:13 caudal migrations with the G2 known to Bard fell into	
	159:14 something that can contribute to death or severe	
	159:15 injury, isn't that something that physicians or	
	159:16 patients needed to know?	
159:18 - 159:18	Wong, Natalie 10-18-2016 (00:00:01)	03_16_18 Combo final3.120
	159:18 THE WITNESS: No, not at this point.	
163:15 - 163:18	Wong, Natalie 10-18-2016 (00:00:07)	03_16_18 Combo final3.121
	163:15 Q. Isn't this -- well -- the first time caudal	
	163:16 anchors were added in a Bard filter was the Meridian.	
	163:17 Correct?	
	163:18 A. I believe so.	
164:9 - 164:13	Wong, Natalie 10-18-2016 (00:00:17)	03_16_18 Combo final3.122
	164:9 Q. Well, as of April 28th, 2006, in your	WONG 544.3.1
	164:10 memorandum right here is a statement about how to	
	164:11 prevent caudal migration. Correct?	
	164:12 A. It's a statement of what Greenfield did to	WONG 544.3.2
	164:13 prevent caudal migration.	
164:19 - 164:23	Wong, Natalie 10-18-2016 (00:00:21)	03_16_18 Combo final3.123
	164:19 Q. Well, if you have this as an -- as an	clear
	164:20 option in 2006, and this is what was ultimately done	
	164:21 on the Meridian, why did it take over five years to	
	164:22 release a product with caudal anchors?	
	164:23 A. I don't know. I wasn't on the team.	
167:18 - 167:20	Wong, Natalie 10-18-2016 (00:00:04)	03_16_18 Combo final3.124
	167:18 Q. Aren't you a -- a part of new product	

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167:19 development?		
167:20 A. Yes.		
167:22 - 168:2	Wong, Natalie 10-18-2016 (00:00:18)	03_16_18 Combo final3,125
167:22 do you not have an		
167:23 understanding of how long it should take to -- to		
167:24 make a change to a product?		
167:25 A. I have an understanding of the steps we		
168:1 need to release a product, but for an implant, like a		
168:2 filter, I don't know what is a reasonable time frame.		
168:3 - 168:5	Wong, Natalie 10-18-2016 (00:00:07)	03_16_18 Combo final3,126
168:3 Q. I mean, you can -- you can come up with --		
168:4 you can go from a new theory of a new device to		
168:5 launch in less than five years. Right?		
168:7 - 168:7	Wong, Natalie 10-18-2016 (00:00:02)	03_16_18 Combo final3,127
168:7 THE WITNESS: Yes.		
168:9 - 168:16	Wong, Natalie 10-18-2016 (00:00:23)	03_16_18 Combo final3,128
168:9 Q. I mean, you can literally get a new device		
168:10 up and running with the bench testing and everything		
168:11 else in less than five years?		
168:12 A. I don't know. I don't know what new test		
168:13 methods we would have needed to develop during that		
168:14 time frame. I don't know the animal studies that we		
168:15 would need to do. I don't know. I wasn't part of		
168:16 filter development.		
168:17 - 168:21	Wong, Natalie 10-18-2016 (00:00:09)	03_16_18 Combo final3,129
168:17 Q. my question's a little		
168:18 different than that. I mean, have you seen products,		
168:19 new products, go from theory to launch in less than		
168:20 five years?		
168:21 A. Yes.		
168:22 - 168:24	Wong, Natalie 10-18-2016 (00:00:07)	03_16_18 Combo final3,130
168:22 Q. And this was essentially the -- Meridian		
168:23 was essentially the same product with caudal anchors		
168:24 added. Correct?		
169:1 - 169:2	Wong, Natalie 10-18-2016 (00:00:02)	03_16_18 Combo final3,131
169:1 THE WITNESS: I don't know. I was not on		
169:2 Meridian.		
170:6 - 170:23	Wong, Natalie 10-18-2016 (00:00:47)	03_16_18 Combo final3,132
170:6 Q. you've been handed what's		WONG 545.1
170:7 marked as Deposition -- and I have no idea -- can you		

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	170:8 tell us what the number is?	
	170:9 A. 545.	
	170:10 Q. Okay. And this is an e-mail from you to	WONG 545.1.1
	170:11 Gin Schulz on July 13th of 2006. Correct?	
	170:12 A. Yes.	
	170:13 Q. And you're attaching the failure	
	170:14 investigation report for caudal migration?	
	170:15 A. Yes.	
	170:16 Q. And what is a failure investigation report?	
	170:17 A. It was an investigation we did to	
	170:18 investigate why the caudal migrations were occurring.	WONG 545.3.1
	170:19 Q. Okay. And if you look on page 2 of 15 of	
	170:20 the caudal migration, it lists -- it lists -- under	
	170:21 2.0 it lists you as the primary investigator.	
	170:22 Correct?	
	170:23 A. Yes.	
175:15 - 175:25	Wong, Natalie 10-18-2016 (00:00:30)	03_16_18 Combo final3.133
	175:15 Q. And then the next bullet point says, "The	WONG 545.11.1
	175:16 overall risk ranking for caudal migration is	
	175:17 considered a 'Quad 3,'" and then the bullet under	
	175:18 that says, "Quad" -- "Quad ranking of 3 equals	
	175:19 significant risk."	
	175:20 Did I read that correctly?	
	175:21 A. Yes.	clear
	175:22 Q. So, Bard, for purposes of its failure modes	
	175:23 effects analysis deemed the overall risk ranking for	
	175:24 caudal migration to be significant; is that fair?	
	175:25 A. Yes.	
176:7 - 176:10	Wong, Natalie 10-18-2016 (00:00:12)	03_16_18 Combo final3.134
	176:7 Q. So, per Bard's -- per Bard's rationale in	
	176:8 this -- in this failure investigation report, the	
	176:9 over -- the -- a caudal migration represents a	
	176:10 significant risk. Fair?	
176:12 - 177:10	Wong, Natalie 10-18-2016 (00:01:32)	03_16_18 Combo final3.135
	176:12 THE WITNESS: Per the DFMEA, it's a	
	176:13 Quad 3 significant risk.	
	176:14 BY MR. DEGREEFF:	
	176:15 Q. Okay. And the DFMEA is -- is what Bard	
	176:16 uses to assess risk. Fair?	
	176:17 A. Yes. It's one of the tools, yes.	

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176:18	Q. Okay. Let's see, will you look at page 14	
176:19	of 15. This is the long -- and look under 10.1, it	
176:20	says -- wait, what am I looking at? Oh, yeah, 10.1,	
176:21	long-term corrective action with regard to G2 caudal	WONG 545.15.1
176:22	migration. It says, "In order to mitigate potential	
176:23	future events related to this phenomenon, the G2	
176:24	filter will be optimized to address these failure	
176:25	modes. The project was initiated in February of	
177:1	2006, and the project number is 8049. Within the	
177:2	project scope, caudal migration test method will be	
177:3	developed to further understand the root cause of	
177:4	caudal migration."	
177:5	Did I read that correctly?	
177:6	A. Yes.	clear
177:7	Q. So in February of 2006, Bard started	
177:8	working on trying to -- trying to optimize its filter	
177:9	to fix the caudal migration issue?	
177:10	A. Yes.	
178:18 - 178:20	Wong, Natalie 10-18-2016 (00:00:04)	03_16_18 Combo final3.136
178:18	Q. During your time on the G2 filter, was a	
178:19	root cause ever identified?	
178:20	A. No.	
179:4 - 179:13	Wong, Natalie 10-18-2016 (00:00:25)	03_16_18 Combo final3.137
179:4	Q. If you look down at -- at 10.3, it says	WONG 545.15.2
179:5	"Preventative Action."	
179:6	A. Yes.	
179:7	Q. Under that it says, "none."	
179:8	A. Yes.	
179:9	Q. So Bard essentially opted to do nothing	
179:10	with regard to preventative action on the caudal	
179:11	migration?	clear
179:12	A. No preventative actions, but there were	
179:13	corrective actions.	
179:19 - 179:22	Wong, Natalie 10-18-2016 (00:00:06)	03_16_18 Combo final3.138
179:19	Q. that doesn't help any, any	
179:20	physicians or patients, unless they're told about the	
179:21	issue. Right?	
179:22	A. Yes.	
180:10 - 180:18	Wong, Natalie 10-18-2016 (00:00:17)	03_16_18 Combo final3.139
180:10	Q. Okay. Well, let's look at that, then.	

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	180:11 Look at the next page, number 13 is the subject	WONG 545.16.1
	180:12 "Product/Remedial Action Recommendation." Right?	
	180:13 A. Yeah.	
	180:14 Q. And the ultimate conclusion was "not	
	180:15 required at this time." Right?	
	180:16 A. Right.	
	180:17 Q. So, again, Bard just -- Bard opted to do	
	180:18 nothing with regard to caudal migration?	
180:20 - 180:24	Wong, Natalie 10-18-2016 (00:00:04)	03_16_18 Combo final3.140
	180:20 THE WITNESS: No, we have corrective	clear
	180:21 actions.	
	180:22 BY MR. DEGREEFF:	
	180:23 Q. Internal corrective actions. Right?	
	180:24 A. Yes.	
181:11 - 181:14	Wong, Natalie 10-18-2016 (00:00:06)	03_16_18 Combo final3.141
	181:11 Q. what they decided	
	181:12 to do with regard to remedial action and preventative	
	181:13 action was nothing. Right?	
	181:14 A. At this time, no.	
181:18 - 181:22	Wong, Natalie 10-18-2016 (00:00:11)	03_16_18 Combo final3.142
	181:18 Q. Preventative actions and remedial actions	
	181:19 would be something that done outside of the company	
	181:20 to actually try to -- try to prevent injuries from	
	181:21 occurring?	
	181:22 A. Yes. There were none.	
184:6 - 185:5	Wong, Natalie 10-18-2016 (00:01:08)	03_16_18 Combo final3.143
	184:6 Q. So does this mean that the G2,	
	184:7 percentagewise, had a greater number of leg	
	184:8 detachments than the RNF?	
	184:9 A. Yes.	
	184:10 Q. And then if you look down further	
	184:11 there's -- it says, "Caudal migration." Correct?	WONG 546.18.1
	184:12 A. Yes.	
	184:13 Q. G2, 14 percent; RNF, 3 percent?	
	184:14 A. Yes.	
	184:15 Q. Comments says, "G2 more caudal than RNF"?	
	184:16 A. Yes.	
	184:17 Q. And this is in November 30th of 2008.	
	184:18 Correct?	
	184:19 A. Yes.	

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184:20 Q. And this was -- this increased rate of
 184:21 caudal migration with the G2 versus the RNF is
 184:22 consistent with everything we looked at in your 2006
 184:23 PowerPoints also. Right?
 184:24 A. Yes, G2 had more caudal than RNF, yes.
 184:25 Q. And caudal migration is an aspect of
 185:1 stability of the filter. Fair?
 185:2 A. Yes.
 185:3 Q. So would it be inaccurate to say that the
 185:4 G2 had increased stability over the Recovery?
 185:5 A. I don't know.

clear

185:6 - 186:7

Wong, Natalie 10-18-2016 (00:01:27)

03_16_18 Combo final3.144

185:6 Q. Well, certainly, with regard to caudal
 185:7 migration, it lacks stability in comparison to the
 185:8 Recovery. Correct?
 185:9 A. In the caudal migration direction.
 185:10 Q. Okay. Well, look at the next one down,
 185:11 cephalad migration, that's -- that's towards the
 185:12 head. Correct?
 185:13 A. Yes.
 185:14 Q. And you've got the G2 and the RNF both have
 185:15 4 percent migration rate, right, cephalad migration
 185:16 rate?
 185:17 A. Yes.
 185:18 Q. And the comment is "same." Correct?
 185:19 A. Yes, I'm just confused, though, with this
 185:20 chart.
 185:21 Q. Well, so you're looking at -- you've got
 185:22 the G2 has a higher rate of migration, of caudal
 185:23 migration rate than the RNF. Right?
 185:24 A. Yes, but I think it might be relative to
 185:25 filter fracture.
 186:1 Q. Well, there's -- there's a separate line
 186:2 item in here that deals with limb detachments.
 186:3 Right?
 186:4 A. Yes, but this packet is for G2 and G2X
 186:5 fracture analysis. So I think these are fractures.
 186:6 And of those fractures, how many were caudal
 186:7 migration in association with the fracture.

WONG 546.18.2

clear

186:8 - 186:15

Wong, Natalie 10-18-2016 (00:00:26)

03_16_18 Combo final3.145

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186:8	Q. Well, wouldn't you say that in here, just	
186:9	like you would say "G2X" if that's what you meant?	
186:10	A. No, I think this is strictly G2. I don't	
186:11	think there's G2X in here, but I think this whole	
186:12	packet is related to filter fracture. So it's filter	
186:13	fracture with caudal migration is 14 percent. With	
186:14	cephalad, it's 4 percent. With tilt it's 39 percent,	
186:15	and with perforation it's 36 percent.	
191:8 - 191:23	Wong, Natalie 10-18-2016 (00:00:30)	03_16_18 Combo final3.146
191:8	Q. You're going to be handed what's been	WONG 547.1
191:9	marked as Deposition Exhibit 547. Have you got that	
191:10	in front of you?	
191:11	A. Yes.	
191:12	Q. And if you look at the very top, there's an	
191:13	e-mail from you to Brian Hudson with the subject	WONG 547.1.1
191:14	line, "FDA Request for Information." Correct?	
191:15	A. Yes.	
191:16	Q. And the date is May 9th of 2006?	
191:17	A. Yes.	
191:18	Q. And there are some attachments to that. It	
191:19	looks like three different attachments?	
191:20	A. Yes.	
191:21	Q. And your e-mail says, "Please see	
191:22	attached"?	
191:23	A. Yes.	
192:25 - 193:14	Wong, Natalie 10-18-2016 (00:01:01)	03_16_18 Combo final3.147
192:25	Q. feel free to review the e-mail below	clear
193:1	that, but it looks like what the FDA is -- is looking	
193:2	for is rate information regarding device failure	
193:3	modes, essentially. Right?	
193:4	A. Yes. They're requesting failure mode rate	
193:5	information.	
193:6	Q. And, specifically, they're requesting rate	
193:7	information with regard to a difficult -- difficulty	
193:8	to deploy, caudal migration, and cephalad migration.	
193:9	Right?	
193:10	A. Yes.	
193:11	Q. And then -- and so what's attached to this	
193:12	e-mail is the draft responses to the FDA. Fair?	
193:13	A. Yeah, I don't think they're complete,	

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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194:18 - 196:13

193:14 though.

Wong, Natalie 10-18-2016 (00:02:34)

03_16_18 Combo final3.148

194:18 Q. And these are two different letters that

194:19 are attached to the -- to this e-mail string

194:20 responding to the FDA on their request for rates --

194:21 A. Yes.

194:22 Q. And this first one regarding caud -- caudal

194:23 migration states, you know, that the -- it begins by

194:24 saying, "The IFU states complications may occur at

194:25 any time during or after the procedure, and potential

195:1 complications include, but are not limited to,

195:2 movement or migration of the filter as a known

195:3 complication of vena cava filters." Right?

195:4 A. Yes.

195:5 Q. And then the second paragraph goes on to

195:6 discuss the DFMEA for this -- for this device that

195:7 was performed with regard to caudal migrations.

195:8 Right?

195:9 A. It discusses the DFMEA, yes.

195:10 Q. Okay. And it starts by saying, as

195:11 designed -- "As defined in the design failure modes

195:12 and effects analysis for this product, the expected

195:13 frequency of occurrence for caudal migration

195:14 resulting in an effect (i.e., severity) similar to

195:15 this complaint is less than or equal to .05 percent."

195:16 Did I read that correctly?

195:17 A. Yes.

195:18 Q. Then it goes on to state, "The observed

195:19 frequency of occurrence is .129 percent (as of April

195:20 30th, 2006), of which none of these events have been

195:21 associated with death. As the actual rate of

195:22 occurrence exceeds the expected rate, the level of

195:23 risk for this specific failure mode was reassessed in

195:24 the DFMEA."

195:25 So let's -- let's stop there for a second.

196:1 So what you're -- what's being said here is the

196:2 expected frequency, as set forth in Bard's DFMEA

196:3 analysis, for caudal migrations similar to this one

196:4 that they're asking about was .05 percent. Correct?

196:5 A. For caudal migration -- yes.

WONG 547.5.1

WONG 547.5.2

clear

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196:6 Q. And then -- but Bard is reporting that
 196:7 the -- the actual observed frequency, meaning what
 196:8 their data has told them, is that the occurrence is
 196:9 .129 percent, as of April 30th of 2006. Right?

196:10 A. Yes.

196:11 Q. And -- and that rate of occurrence exceeds
 196:12 the expected rate?

196:13 A. Yes.

196:23 - 198:9

Wong, Natalie 10-18-2016 (00:02:23)

03_16_18 Combo final3.149

196:23 Q. So my question was, the -- the actual --
 196:24 what the FDA's being told by Bard is that the actual
 196:25 observed frequency of occurrence exceeds the
 197:1 expected -- the expected rate of occurrence under the
 197:2 DFMEA analysis?

197:3 A. Yes.

197:4 Q. And if that occurs, that means that it's an
 197:5 unacceptable risk and action needs to be taken.
 197:6 Right?

197:7 A. Yes.

197:8 Q. And so -- but what Bard then says, and this
 197:9 is the part I'm confused about and need your help
 197:10 with is, "As the actual rate of occurrence exceeds
 197:11 the expected rate, the level of risk for this
 197:12 specific failure mode was reassessed in the DFMEA.
 197:13 Upon secondary assessment, the overall risk level,
 197:14 which consists of occurrence, severity, and
 197:15 detection, remains below the risk threshold. The
 197:16 risk remains at an acceptable level per BVV's [sic]
 197:17 risk management assessment team."

WONG 547.5.3

197:18 Did I read that correctly?

197:19 A. Yes.

197:20 Q. So what I -- what I think this says is that
 197:21 Bard's product failed Bard's DFMEA as to caudal
 197:22 migration, so they just reassessed it so they would
 197:23 pass; is that correct?

clear

197:24 A. We reassessed it, I -- I'm trying to think
 197:25 of the timeline here, because in the initial DFMEA
 198:1 for G2, caudal wasn't separated out for migration.
 198:2 So I'm not exactly sure where that .05 came from. I
 198:3 would have to look at the DFMEA, because the DFMEA's

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	198:4 also typed out as well.	
	198:5 So I don't know if that -- because the	
	198:6 DFMEA's typed out, the typing the one through four,	
	198:7 that we saw earlier, I don't know what that .05	
	198:8 refers to, because the FDA question is related to the	
	198:9 observed frequency and severity of that occurrence.	
199:12 - 200:13	Wong, Natalie 10-18-2016 (00:01:06)	03_16_18 Combo final3,150
	199:12 Q. This document actually	
	199:13 states that the actual rate of occurrence exceeds the	
	199:14 expected rate. Right?	
	199:15 A. Yes.	
	199:16 Q. So, I mean, there's not -- there's not	
	199:17 really a question about that. Right?	
	199:18 A. Right.	
	199:19 Q. So then they -- then they go on to say that	
	199:20 they -- they reassessed it, and what they basically	
	199:21 say is, well, we failed, but then we went back and we	
	199:22 reassessed so now we passed, so it's okay. Right?	
	199:23 A. I would want to know what that secondary	
	199:24 reassessment looked like. I don't remember.	
	199:25 Q. Okay. Well, let's move on to the next	
	200:1 paragraph. The next paragraph, if you look at,	
	200:2 starting on sentence two, and this is that same	
	200:3 letter regarding caudal migrations, it says, "For the	
	200:4 clinically relevant threshold (2 percent) for	
	200:5 migration, one should consider the Society of	
	200:6 Interventional Radiologists' quality improvement	
	200:7 guidelines."	
	200:8 Do you see that?	
	200:9 A. Yes.	
	200:10 Q. Didn't we discuss earlier about the fact	
	200:11 that Bard didn't consider the SIR guidelines to be a	
	200:12 threshold?	
	200:13 A. Yes.	
201:5 - 201:15	Wong, Natalie 10-18-2016 (00:00:27)	03_16_18 Combo final3,151
	201:5 Q. it's your understanding of the	
	201:6 SIR guidelines as the -- one of the people that's in	
	201:7 new product development and a member of the quality	
	201:8 engineering team, that the SIR guidelines represent a	
	201:9 threshold for migra -- for caudal migration?	

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	201:10 A. There's threshold numbers in the SIR	
	201:11 guidelines, but we set our own internal threshold to	
	201:12 be lower than that.	
	201:13 Q. You set your own internal threshold lower	
	201:14 than the SIR guidelines?	
	201:15 A. Yeah, which -- yeah.	
201:16 - 202:11	Wong, Natalie 10-18-2016 (00:01:06)	03_16_18 Combo final3.152
	201:16 Q. Then why would Bard	
	201:17 tell the FDA that the SIR thresh -- SIR guidelines	
	201:18 thresholds were -- were important?	
	201:19 A. Because I think that's what was out there	
	201:20 in industry was this SIR guidelines.	
	201:21 Q. Isn't it more likely that it's because Bard	
	201:22 failed its own internal threshold, so it had to come	
	201:23 up with some threshold that it passed?	
	201:24 A. I don't know.	
	201:25 Q. That's certainly possible, isn't it?	
	202:1 A. It is possible, but I think the SIR	
	202:2 guidelines are what industry was saying is clinically	
	202:3 relevant threshold percentage.	WONG 547.6.1
	202:4 Q. And if you look at -- so, there was a	
	202:5 threshold of 2 percent, as reported to the FDA here?	
	202:6 You see the threshold -- movement migration,	
	202:7 threshold from SIR guidelines 2 percent?	
	202:8 A. Yes.	
	202:9 Q. That would mean it was acceptable for 1 in	
	202:10 50 -- for 1 in 50 filters to migrate. Right?	
	202:11 A. Yes, per the guidelines.	
202:12 - 202:15	Wong, Natalie 10-18-2016 (00:00:14)	03_16_18 Combo final3.153
	202:12 Q. Does that sound acceptable to you?	clear
	202:13 A. I don't know. It's -- I think it's up to	
	202:14 the physician to under -- to determine what's	
	202:15 significantly -- what's a significant migration.	
202:18 - 203:8	Wong, Natalie 10-18-2016 (00:00:35)	03_16_18 Combo final3.154
	202:18 Q. My question is, does 1 in 50 filter	
	202:19 migrations sound like something that Bard would deem	
	202:20 acceptable?	
	202:21 A. No.	
	202:22 Q. But -- but here Bard is telling the FDA	
	202:23 that's an acceptable threshold?	

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202:24 A. From industry guidelines, SIR guidelines.

202:25 Q. Yeah, but Bard --

203:1 A. But we're not close to that number, we're

203:2 at .129 percent.

203:3 Q. Yeah, but my question is, I mean, here Bard

203:4 is telling the FDA that a clinically relevant

203:5 threshold for migration is 2 percent, but yet

203:6 internally applying a much stricter threshold.

203:7 Right?

203:8 A. Yes.

203:9 - 203:14

Wong, Natalie 10-18-2016 (00:00:17)

03_16_18 Combo final3.155

203:9 Q. Why would you need to pass

203:10 on that -- that 2 percent threshold to the FDA,

203:11 unless it was because Bard didn't pass its own

203:12 internal thresholds?

203:13 A. I mean, I know we set our -- ours more

203:14 rigorous.

204:1 - 205:2

Wong, Natalie 10-18-2016 (00:01:13)

03_16_18 Combo final3.156

204:1 Q. Well, let's look at the next

204:2 paragraph down, it says, "Per table 1 above, BPV's

204:3 overall migration rate is within the range of

204:4 reported (0 to 18 percent), and below the threshold

204:5 (2 percent) rates, as described in the SIR quality

204:6 improvement guidelines. In conclusion, the G2 filter

204:7 migration rate is below the risk threshold per BPV's

204:8 internal risk management system, and is below the

204:9 event rates and threshold reported in the SIR quality

204:10 improvement guidelines."

204:11 Did I read that correctly?

204:12 A. Yes.

204:13 Q. So Bard is certainly using the

204:14 SIR threshold here as the threshold -- one of the

204:15 threshold rates that it is better than. Correct?

204:16 A. Yes.

204:17 Q. But yet it's not using that internally as a

204:18 threshold. Right?

204:19 A. No.

204:20 Q. And Bard would never consider 1 in 50

204:21 filters migrating to be -- to be a reasonable

204:22 standard, would they?

WONG 547.6.2

clear

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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204:23 A. No, which is why we set ours lower.
 204:24 Q. Okay. And it then says that Bard's G2
 204:25 filter migration rate is below the risk threshold per
 205:1 its risk management system. Right?
 205:2 A. Yes.

205:3 - 205:8

Wong, Natalie 10-18-2016 (00:00:15)

03_16_18 Combo final3.157

205:3 Q. Well, that's not right. I know -- we know
 205:4 that it -- we know that it initially failed it until
 205:5 it did the reassessment. Right?
 205:6 A. But I need to look at the DFMEA, to see if
 205:7 we increased our overall risk profile, because I -- I
 205:8 can't derive that from this paragraph.

205:9 - 206:1

Wong, Natalie 10-18-2016 (00:00:46)

03_16_18 Combo final3.158

205:9 Q. So basically what we've got here is
 205:10 they're -- they're telling -- they're telling the
 205:11 FDA -- Bard's telling the FDA everything's --
 205:12 everything's okay with caudal migration rates,
 205:13 because we failed our own internal DFMEA, but we
 205:14 reassessed, so it's okay, we passed now. And we're
 205:15 lower than the 1 in 50 migration threshold set by the
 205:16 SIR. Right?
 205:17 A. I need to look at that DFMEA again.
 205:18 Q. That's not exactly what they're saying, I
 205:19 mean, that's essentially what they're saying. Right?
 205:20 A. They're saying we're within our risk
 205:21 thresholds for our internal risk management system,
 205:22 and we're below the thresholds within the SIR.
 205:23 Q. Okay. And we're talking about an analysis
 205:24 that they admit right here that the actual rate of
 205:25 occurrence exceeds the expected rate. Right?

206:1 A. Yes.

206:2 - 206:10

Wong, Natalie 10-18-2016 (00:00:19)

03_16_18 Combo final3.159

206:2 Q. But it's cool, because we reassessed.
 206:3 Right?
 206:4 A. No, it's not. We reevaluated it, but I
 206:5 need to see that DFMEA to see what that means.
 206:6 Q. As you sit here as the person who was in
 206:7 charge of the G2 caudal migration failure
 206:8 investigation, you don't remember anything about
 206:9 that?

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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206:11 - 206:14	206:10 A. I need to go back to the document. Wong, Natalie 10-18-2016 (00:00:14)	03_16_18 Combo final3,160
	206:11 Q. Looking at the next letter, this is	
	206:12 the -- this is the cranial migration response.	
	206:13 Correct?	
206:15 - 206:15	206:14 A. Yes. Wong, Natalie 10-18-2016 (00:00:01)	03_16_18 Combo final3,161
206:18 - 206:22	206:15 Q. what they say here is, Wong, Natalie 10-18-2016 (00:00:19)	03_16_18 Combo final3,162
	206:18 "design failure modes and effects analysis	WONG 547.7.2
	206:19 for this product, the expected frequency of	
	206:20 occurrence for a cephalad migration, resulting in an	
	206:21 effect (i.e., severity) similar to this complaint, is	
206:23 - 207:3	206:22 less than or equal to .05 percent." Wong, Natalie 10-18-2016 (00:00:11)	03_16_18 Combo final3,163
	206:23 I read that correctly. Right?	
	206:24 A. Yes.	
	206:25 Q. And it then says "The observed frequency of	WONG 547.7.3
	207:1 occurrence is .016 percent as of April 30th, 2006."	
	207:2 Right?	
	207:3 A. Yes.	
209:15 - 209:22	Wong, Natalie 10-18-2016 (00:00:22)	03_16_18 Combo final3,164
	209:15 Q. I mean, you were in charge of G2 caudal	clear
	209:16 migration failure investigation. Right?	
	209:17 A. Yes.	
	209:18 Q. So you can't point me to some data saying	
	209:19 caudal migrations are not as bad as cephalad?	
	209:20 A. The data is the complaint data.	
	209:21 Q. Okay.	
	209:22 A. And the resulting severities of those.	
218:6 - 219:4	Wong, Natalie 10-18-2016 (00:01:08)	03_16_18 Combo final3,165
	218:6 Q. And another document, 545, can you	WONG 545.1
	218:7 get that exhibit, please.	
	218:8 A. Yes.	
	218:9 Q. And look at -- if you look at the page 14	WONG 545.15
	218:10 of 15, you and Mr. Degreeff talked about this a	
	218:11 little bit. See where -- see the word "optimized,"	WONG 545.15.4
	218:12 "The long-term corrective action in order to mitigate	
	218:13 potential future events related to this phenomenon,	
	218:14 the G2 filter will be optimized."	

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	218:15 Do you see where I am?	
	218:16 A. Yes.	
	218:17 Q. And that means it needs to be redesigned,	
	218:18 right?	
	218:19 A. It means to make improvements.	
	218:20 Q. You need to fix it? You need to make it	clear
	218:21 better, how's that?	
	218:22 A. Yes.	
	218:23 Q. You -- you need to figure out what you need	
	218:24 to do to the design of the G2 to mitigate the	
	218:25 potential future events of caudal migration.	
	219:1 Correct?	
	219:2 A. Yes, and --	
	219:3 Q. Pardon me?	
	219:4 A. And to prevent other failure modes.	
219:8 - 219:12	Wong, Natalie 10-18-2016 (00:00:14)	03_16_18 Combo final3.166
	219:8 Here, optimize means we have to do something	
	219:9 to the G2 filter, from a design perspective, to make	
	219:10 it better to see if we can make this caudal migration	
	219:11 go away or at least minimize it. True?	
	219:12 A. Yes.	
219:17 - 219:20	Wong, Natalie 10-18-2016 (00:00:05)	03_16_18 Combo final3.167
	219:17 Q. And one way to avoid the risk while you're	
	219:18 redesigning it would be to just stop selling it.	
	219:19 Correct?	
	219:20 A. Yes.	
220:6 - 220:10	Wong, Natalie 10-18-2016 (00:00:32)	03_16_18 Combo final3.168
	220:6 Exhibit 537, we're going to spend	WONG 537.1.1
	220:7 some time on 537. Okay? That's the one where the	
	220:8 front e-mail is a May 27, 2004 e-mail from Doug	
	220:9 Uelmen to Kellee Jones. Do you see where I am?	
	220:10 A. 537, yes.	
220:14 - 220:22	Wong, Natalie 10-18-2016 (00:00:19)	03_16_18 Combo final3.169
	220:14 Q. I want to make	clear
	220:15 sure the jury understands who he is, Doug Uelmen	
	220:16 worked for C. R. Bard. Correct?	
	220:17 A. Yes.	
	220:18 Q. And he was in corporate?	
	220:19 A. At this time, he was my VP of quality.	
	220:20 Q. Okay. At BPV or was he a C. R. Bard	

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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220:21 employee?		
220:22 A. At BPV.		
231:4 - 231:18	Wong, Natalie 10-18-2016 (00:00:28)	03_16_18 Combo final3,170
231:4 Q. And then in the left-hand column, you		WONG 537.7.6
231:5 listed the Recovery filter, along with each of the		
231:6 other filters to which it was compared in your		
231:7 analysis. Correct?		
231:8 A. Yes.		
231:9 Q. So you were running this analysis to do a		
231:10 comparison between the Recovery filter and all of		
231:11 these other filters. That was the purpose of the		
231:12 analysis?		
231:13 A. Yes.		
231:14 Q. And -- and you were going to see if -- if		
231:15 the analysis would come up with some statistically		
231:16 significant differences as it relates to fatalities.		
231:17 True?		
231:18 A. Yes.		
232:19 - 233:12	Wong, Natalie 10-18-2016 (00:00:59)	03_16_18 Combo final3,171
232:19 Q. Is it correct that the averages in those		WONG 537.7.7
232:20 columns reflect the percentages calculated by		
232:21 dividing the combined total sales for each device		
232:22 into the number of adverse events for all of the		
232:23 sample periods?		
232:24 A. I don't remember how I calculated the		
232:25 average, I don't know if I used the percent or if I		
233:1 used the raw number.		
233:2 Q. But the average that you calculated for		
233:3 Recovery is 0.031 -- I'm sorry, let me start over.		
233:4 The average that you calculated for Recovery is		
233:5 0.0371 percent. Correct?		
233:6 A. Yes.		
233:7 Q. And that was higher than the average for		
233:8 any other filter on your table. True?		
233:9 A. Yes.		
233:10 Q. Is it correct you calculated a reporting		WONG 537.7.8
233:11 rate percentage of 0.001 percent for Greenfield?		
233:12 A. Yes.		
234:7 - 234:11	Wong, Natalie 10-18-2016 (00:00:13)	03_16_18 Combo final3,172
234:7 Q. you know enough about being involved in		clear

03_16_18 Combo final3-Wong 10-18-16 Booker Depo Designations final3

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234:8 - 234:13	234:8 this industry that Recovery doesn't even get to be 234:9 marketed unless it's -- it is at least as safe and 234:10 effective as its predicate device, here the Simon 234:11 Nitinol filter. Right? Wong, Natalie 10-18-2016 (00:00:01)	03_16_18 Combo final3,173
249:13 - 250:9	234:13 THE WITNESS: Yes. Wong, Natalie 10-18-2016 (00:01:13) 249:13 Q. Okay. 549 is an e-mail -- well, it 249:14 actually is -- yes, it is an e-mail, dated May 27, 249:15 2004 from Natalie Wong to Doug Uelmen. Does this 249:16 help refresh your recollection as to whether or not 249:17 you might have actually gotten more involved in this 249:18 analysis and procedure than after May 21? 249:19 A. I think -- yeah, I remember -- I remember 249:20 seeing this e-mail now. 249:21 Q. And you wrote -- and you wrote this e-mail 249:22 to Mr. Uelmen on May 27, 2004? 249:23 A. Yes. 249:24 Q. And it's -- the subject matter is Recovery 249:25 stats. Right? 250:1 A. Yes. 250:2 Q. And do you see where you report to Doug 250:3 that you're "using the criteria you indicated this 250:4 morning," meaning Doug. Right? 250:5 A. Yes. 250:6 Q. "I have evaluated the data." Right? 250:7 A. Yes. 250:8 Q. So he's having you evaluate more data? 250:9 A. Yes. Wong, Natalie 10-18-2016 (00:00:20)	03_16_18 Combo final3,174 WONG 549.1.1 WONG 549.1.2 WONG 549.1.6
251:24 - 252:9	251:24 Q. didn't you 251:25 assume when you got this that there was one more 252:1 death that was going to be counted for this analysis? 252:2 A. No, I think he was just asking me to rerun 252:3 the numbers with the volume of 13,000 and another 252:4 datapoint. 252:5 Q. Of one failure? 252:6 A. Of one failure. 252:7 Q. What did you think that failure was? 252:8 A. I don't know. It would have been death,	03_16_18 Combo final3,175 clear WONG 549.1.4

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252:13 - 254:5

252:9 given the data that was provided.

Wong, Natalie 10-18-2016 (00:01:56)

03_16_18 Combo final3.176

clear

252:13 Q. He wanted you to run an

252:14 additional analysis. Right?

252:15 A. Yes.

252:16 Q. And did -- did he -- did he tell you that

252:17 he had learned of an additional death report with

252:18 Recovery after he last spoke to you?

252:19 A. He didn't tell me that.

252:20 Q. Did he tell you he wanted to see what the

252:21 results would be if that death case was added to your

252:22 analysis?

252:23 A. I think that's why he asked me to look at

252:24 the data again.

252:25 Q. And you evaluated the data. Correct?

253:1 A. Yes.

WONG 549.1.5

253:2 Q. And you tell Mr. Uelmen that at a 95

253:3 percent confidence, there is not a significant

253:4 difference between Recovery and TrapEase and OptEase.

253:5 Do you see that?

253:6 A. Yes.

253:7 Q. Okay. That's different than what you had

253:8 reported earlier. Right?

253:9 A. Yes, and I think it's because of the

253:10 addition, with the new assumptions.

clear

253:11 Q. Right. So as more data's coming in, you're

253:12 being provided -- you're using the same computer

253:13 program to see if you can come up with statistical

253:14 significance, 95 percent confidence level. True?

253:15 A. Yes.

253:16 Q. And if you look at the -- at the last

253:17 exhibit, this was seven days earlier, now with this

253:18 additional information, the Greenfield and the

253:19 VenaTech are taken out of the not significant

253:20 difference category and they're added to the

253:21 significant difference category. True?

253:22 A. Yes.

253:23 Q. So now, seven days later, with one

253:24 additional death, at 95 percent confidence, there is

253:25 a significant difference between Recovery and

Page/Line	Source	ID
	254:1 Greenfield, Glnther Tulip, Birds Nest filter, SNF, 254:2 and VenaTech. Correct? 254:3 A. Yes. 254:4 Q. As it relates to fatalities. Right? 254:5 A. Yes.	
254:21 - 255:14	Wong, Natalie 10-18-2016 (00:00:46) 254:21 Q. Okay. I mean, did you know as of May of 254:22 2004, they were actually in the process of 254:23 redesigning the Recovery filter because they knew 254:24 they had a crisis with respect to its propensity to 254:25 migrate and fracture? 255:1 A. I didn't know that at that point. 255:2 Q. You found that out at some point. Right? 255:3 A. Yeah, some point later. 255:4 Q. That this thing was not designed to take 255:5 care of the type of -- type of clots that it was 255:6 designed to take care of. You learned that. Right? 255:7 A. Yes. 255:8 Q. But yet it continued to sell the product, 255:9 knowing that it had design issues and failures. 255:10 True? 255:11 A. Yes. 255:12 Q. And it didn't stop until it had the G2 255:13 filter available to -- to market? 255:14 A. Yes.	03_16_18 Combo final3.177
257:2 - 257:17	Wong, Natalie 10-18-2016 (00:00:47) 257:2 Q. So then, as of May 27, 2004, the Recovery's 257:3 reporting rate for death events was statistically 257:4 significantly higher than five of the seven other 257:5 filters on the market. Right? True? 257:6 A. Compared to five -- 257:7 Q. Five other -- 257:8 A. Yes. 257:9 Q. Five other devices on the market? 257:10 A. Yes. 257:11 Q. And -- and even though there was not 257:12 statistical significance in comparing it to the two 257:13 other filters, the TrapEase and the OptEase, just 257:14 from a pure comparative analysis, the Recovery filter 257:15 was causing more fatalities than the TrapEase and the	03_16_18 Combo final3.178

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257:16	OptEase based on the data you had. True?	
257:17	A. Yes.	
264:22 - 265:21	Wong, Natalie 10-18-2016 (00:01:25)	03_16_18 Combo final3,179
264:22	Q. even with the additional datapoints and	
264:23	additional data with respect to the Recovery filter,	
264:24	it -- it continued to show the statistically	
264:25	significant difference in fatalities between it and	
265:1	not only the filters that were on -- that were listed	
265:2	in May, but actually two more filters, when it comes	
265:3	to fatalities?	
265:4	A. I think -- I don't know if it's two more	
265:5	filters. It's inclusive of the ones I found in May.	
265:6	Q. And plus two. Plus the Greenfield and the	
265:7	VenaTech. Right?	
265:8	A. Oh, yes. Yes.	
265:9	Q. And just so we don't lose sight of this,	
265:10	the data that was run in comparing the Recovery	
265:11	filter to the Simon Nitinol filter was not MAUDE	
265:12	data, was not IMS data, but it was actual complaint	
265:13	data and actual sales data that Bard had in its	
265:14	possession. True?	
265:15	A. I believe that to be true.	
265:16	Q. You didn't have to worry about whether or	
265:17	not some other company was inaccurately reporting	
265:18	their sales or inaccurately reporting their deaths.	
265:19	This was a head-to-head comparison of actual data	
265:20	that Bard had themselves. True?	
265:21	A. Yes.	
287:20 - 288:12	Wong, Natalie 10-18-2016 (00:00:36)	03_16_18 Combo final3,182
287:20	Q. So somebody asked you for the data	
287:21	comparing the Recovery filter to the Simon Nitinol	
287:22	filter. Right?	
287:23	A. Yes.	
287:24	Q. And do you know -- did they tell you why	
287:25	that was important?	
288:1	A. I think we were just doing comparison.	
288:2	Q. I know, but did they tell you why the --	
288:3	why the Simon Nitinol filter?	
288:4	A. I think that's the other -- that's the only	
288:5	other filter we had at the time.	

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288:6 Q. Well, could it be because it was the
 288:7 predicate filter too?
 288:8 A. Yes.
 288:9 Q. And could it be because the best data that
 288:10 you had for doing comparisons was the Recovery filter
 288:11 data and the Simon Nitinol filter data?
 288:12 A. Yes.

288:15 - 289:3

Wong, Natalie 10-18-2016 (00:00:38)

03_16_18 Combo final3.183

288:15 are you the one
 288:16 who ran this, these statistics, in other words, is
 288:17 this your count?
 288:18 A. Yes.
 288:19 Q. And you determined that as of January 31,
 288:20 '06, that in the lifetime of the Recovery filter,
 288:21 there were 95 fractures, including one in a clinical
 288:22 trial, and the Simon Nitinol filter as of the third
 288:23 quarter of 2005 had three fractures. Right?
 288:24 A. Yes.
 288:25 Q. And the Simon Nitinol filter had been on
 289:1 the market for at least 10 years longer than the
 289:2 Recovery filter. Right?
 289:3 A. I don't remember.

Plaintiffs Designations = 01:03:46

Defense Designations = 00:13:03

Plaintiffs and Defense Designations = 00:03:51

Total Time = 01:20:40**Documents Shown**

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EXHIBIT C

Designation Run Report

Hudnall 11-01-13 Booker Depo Designations final4

Hudnall, Janet 11-01-2013

Plaintiffs Designations 00:25:31

DefenseDesignations 00:03:47

P & D Designations 00:00:18

Total Time 00:29:36



03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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5:20 - 5:22	Hudnall, Janet 11-01-2013 (00:00:03) 5:20 Q. Could you state your full name for the 5:21 record, please? 5:22 A. Janet Hudnall.	03_13_18 combo final4.1
17:4 - 17:20	Hudnall, Janet 11-01-2013 (00:00:33) 17:4 Q. when you were 17:5 at Bard, in addition to your salary, was there any 17:6 incentive or bonus or -- 17:7 A. There was a bonus program. 17:8 Q. Okay. How did the bonus program work at 17:9 Bard? 17:10 A. 25 percent of the annual salary. 17:11 Q. Based on what kind of performance? 17:12 A. Based on -- based on meeting company or 17:13 the divisional objectives, as well as personal 17:14 objectives, for the year. 17:15 Q. Okay. And was it -- was that across the 17:16 product line of Bard, C.R. Bard? 17:17 A. What does that mean? 17:18 Q. In other words, it -- it was a 17:19 performance-based bonus, right? 17:20 A. Performance-based bonus, yes.	03_13_18 combo final4.2
21:2 - 21:4	Hudnall, Janet 11-01-2013 (00:00:04) 21:2 Q. When did you first become involved in any 21:3 capacity with IVC filters? 21:4 A. 2002.	03_13_18 combo final4.3
35:1 - 35:10	Hudnall, Janet 11-01-2013 (00:00:31) 35:1 Q. Distinguish for me the difference between 35:2 sales and marketing at Bard. 35:3 A. The difference between sales and marketing 35:4 is salespeople go out and get orders and get -- and 35:5 actually -- actually execute the transaction to get 35:6 the revenue. 35:7 Marketing people set the strategy for the 35:8 product line and are responsible for the 35:9 commercialization of the product and transfer of 35:10 the product to the salespeople.	03_13_18 combo final4.4
35:16 - 35:19	Hudnall, Janet 11-01-2013 (00:00:10) 35:16 Q. You have also been described as the 35:17 liaison between the company and its customers; is	03_13_18 combo final4.5

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35:18 that a fair representation of what you did?
 35:19 A. Myself among others, yes.
 36:4 - 36:11 **Hudnall, Janet 11-01-2013 (00:00:18)** 03_13_18 combo final4.6
 36:4 Q. Do you know if the sales representatives
 36:5 or the sales managers were incentivized by reaching
 36:6 particular sales volumes or quotas?
 36:7 A. Yes, yes.
 36:8 Q. Do you know how that worked?
 36:9 A. No.
 36:10 Q. It was based on a quota or a volume?
 36:11 A. Probably. That's how it usually works.
 44:14 - 44:15 **Hudnall, Janet 11-01-2013 (00:00:03)** 03_13_18 combo final4.9
 44:14 Q. Do you know what a 510 application is?
 44:15 A. A 510(k)?
 44:18 - 45:9 **Hudnall, Janet 11-01-2013 (00:00:31)** 03_13_18 combo final4.10
 44:18 Q. Yeah, 510(k) application is?
 44:19 A. Yes.
 44:20 Q. What is it?
 44:21 A. It's a premarket authorization to
 44:22 commercialize a device based on the fact that it's
 44:23 substantially equivalent to a device that's already
 44:24 on the market.
 44:25 Q. And -- and what did you -- what did you
 45:1 understand substantial equivalence to mean?
 45:2 A. Substantial equivalence means that it's
 45:3 not any worse than the device that's out there
 45:4 previously.
 45:5 Q. In other words, that it's -- it's -- when
 45:6 you say "not any worse," it's at least as safe --
 45:7 A. Correct.
 45:8 Q. -- and at least as effective, right?
 45:9 A. Right.
 53:12 - 53:20 **Hudnall, Janet 11-01-2013 (00:00:24)** 03_13_18 combo final4.11
 53:12 Q. And as a marketing person, didn't
 53:13 you learn somewhere along the line that the
 53:14 benefit/risk decisions about using a medical device
 53:15 or any product with -- with a patient is that
 53:16 within the exclusive province of the physician and
 53:17 the patient?
 53:18 A. You're right. You're right about that.

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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54:3 - 54:8

53:19 And it's the company's responsibility to give them
53:20 the information required to make that assessment.

Hudnall, Janet 11-01-2013 (00:00:18)

03_13_18 combo final4.12

54:3 well, first of all, before I move on to that, the
54:4 reason doctors have to know the risks and the
54:5 benefits of a product is so that they can make
54:6 informed decisions about a variety of therapeutic
54:7 options they may have for a patient, correct?
54:8 A. Correct.

55:16 - 56:8

Hudnall, Janet 11-01-2013 (00:00:34)

03_13_18 combo final4.13

55:16 Q. Well, for example, I mean, you -- you have
55:17 a sales force to go out and -- and discuss fair --
55:18 in a fair, balanced way the benefits and risks of
55:19 products, right, while you were at Bard?
55:20 A. Yes.
55:21 Q. And you know what fair balance means?
55:22 A. Yes.
55:23 Q. That means you can't go in and just talk
55:24 about all the wonderful things the product can do,
55:25 right?
56:1 A. Yes.
56:2 Q. You have to talk about what some of the
56:3 downside risks are, right?
56:4 A. Yes.
56:5 Q. And sometimes, that you have to expose
56:6 risks that are -- that may even put you at a
56:7 disadvantage with a competitor?
56:8 A. Sure.

56:15 - 56:23

Hudnall, Janet 11-01-2013 (00:00:20)

03_13_18 combo final4.14

56:15 Q. Well, in other words, you shouldn't hold
56:16 back information you have about risks just to
56:17 maintain a competitive advantage over someone when
56:18 you know that's the kind of risk a physician needs
56:19 to know for him to do a benefit risk analysis?
56:20 A. Sure. Of course not.
56:21 Q. And the message needs to be honest at all
56:22 times?
56:23 A. Yes.

56:24 - 57:12

Hudnall, Janet 11-01-2013 (00:00:44)

03_13_18 combo final4.16

56:24 Q. And part of your position as a marketing

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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56:25 person at Bard, in addition to you knowing what
 57:1 type of things a physician might like about a
 57:2 product for purposes of using it, it was your job
 57:3 to also understand what are some of the things
 57:4 physicians would like to know about relative risks
 57:5 and the severity and frequency of risks to
 57:6 determine whether or not to use the product, right?
 57:7 A. Yes.

57:8 Q. And in a competitive market, it would be
 57:9 wrong to downplay your risks against a competitor
 57:10 when you had -- if you had information that your
 57:11 risks were actually greater than the competitor;
 57:12 would you agree with that?

57:14 - 57:16

Hudnall, Janet 11-01-2013 (00:00:06)

03_13_18 combo final4.17

57:14 THE WITNESS: If we had information that
 57:15 the risks that -- if the risks were actually
 57:16 greater, yes, it would be wrong.

67:9 - 67:13

Hudnall, Janet 11-01-2013 (00:00:24)

03_13_18 combo final4.18

67:9 Q. And by the way, has Bard ever done a study
 67:10 that you know of that established that you can
 67:11 safely remove a Recovery or G2 filter after a year?
 67:12 A. That specific endpoint? No. You have to
 67:13 leave it open.

99:1 - 100:5

Hudnall, Janet 11-01-2013 (00:01:28)

03_13_18 combo final4.19

99:1 Q. And it talks about, see here, it says,
 99:2 "Bard's Simon Nitinol filter has maintained its
 99:3 market share position at 11 to 12 percent"?
 99:4 A. Yes.

HUDNALL20.4.1

99:5 Q. So in other words, even though some of
 99:6 these other products were coming on the market and
 99:7 affecting the sales of Greenfield, the Simon
 99:8 Nitinol filter seemed to be maintaining its market
 99:9 share?

99:10 A. Yes.

HUDNALL20.4.2

99:11 Q. And then you wrote, "However, we will need
 99:12 to introduce a new device with clear advantages in
 99:13 order to maintain and grow our IVC market business
 99:14 moving forward." You wrote that?

99:15 A. Yes, I did.

99:16 Q. And what did you mean by that?

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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99:17 A. Just what it says.

99:18 Q. In other words, if you wanted to capture
99:19 more than 11 or 12 percent of the market share in
99:20 the IVC filter arena, you'd have to come up with a
99:21 new device?

99:22 A. New device, yes.

99:23 Q. With clear advantages?

99:24 A. Yes.

99:25 Q. And what -- what do you mean by

100:1 "advantages"?

100:2 A. Advantages -- advantages, it's hard to
100:3 explain things that are so basic. "Advantages"
100:4 meaning lower profile, retrievable, just next
100:5 generation devices.

100:14 - 100:23

Hudnall, Janet 11-01-2013 (00:00:15)

03_13_18 combo final4.20

100:14 Q. By the way, what does "lower profile"
100:15 mean?

100:16 A. It's smaller in diameter.

100:17 Q. Smaller in diameter?

100:18 A. Yes.

100:19 Q. Why would -- why would that be an
100:20 advantage?

100:21 A. Because you want a smaller entry site so
100:22 that you have a smaller wound in your -- in your
100:23 skin.

101:4 - 101:9

Hudnall, Janet 11-01-2013 (00:00:13)

03_13_18 combo final4.21

HUDNALL20.4.6

101:4 Q. And then you wrote, "Users can be swayed
101:5 by ease of use, low profile, and aggressive
101:6 marketing, even in the absence of solid clinical
101:7 history and in spite of documented negative
101:8 clinical experiences"?

101:9 A. Yes.

101:10 - 101:22

Hudnall, Janet 11-01-2013 (00:00:42)

03_13_18 combo final4.22

clear

101:10 Q. And how did you learn that?

101:11 A. Through the Cordis TrapEASE experience.

101:12 Q. And so if you were to -- to develop a
101:13 product that was -- had -- was ease of use -- or
101:14 that was easy to use and had a low profile that you
101:15 just talked about, and even if it had documented
101:16 negative clinical experiences, aggressive marketing

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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	101:17 could still make that a successful product? 101:18 A. What I was talking about here is that 101:19 these are the market conditions I am describing. 101:20 This is not a plan of action here. These are the 101:21 market conditions. So users can be swayed. They 101:22 have been swayed.	
108:2 - 108:8	Hudnall, Janet 11-01-2013 (00:00:23) 108:2 Q. as a marketer and the person in charge 108:3 of marketing the Recovery and the G2 -- the G2 and 108:4 the Recovery line of products until you left, it 108:5 would be wrong and unethical to, if you had a 108:6 negative clinical experience with those devices, to 108:7 just use aggressive marketing to continue to sell 108:8 them, right?	03_13_18 combo final4.23
108:10 - 108:11	Hudnall, Janet 11-01-2013 (00:00:07) 108:10 THE WITNESS: It would be wrong if we were 108:11 providing a lot of risks without any benefits, yes.	03_13_18 combo final4.24
108:13 - 108:17	Hudnall, Janet 11-01-2013 (00:00:11) 108:13 If there was documented 108:14 negative clinical experience, for you to ignore 108:15 that and just use aggressive marketing to -- 108:16 A. To ignore it would be wrong. 108:17 Q. Okay. And to continue to sell it?	03_13_18 combo final4.25
108:19 - 108:22	Hudnall, Janet 11-01-2013 (00:00:07) 108:19 THE WITNESS: To ignore it would be wrong. 108:20 Q. BY MR. LOPEZ: And to not maybe share that 108:21 with physicians would be wrong, too, correct? 108:22 A. Yes.	03_13_18 combo final4.26
108:23 - 109:2	Hudnall, Janet 11-01-2013 (00:00:18) 108:23 Q. And out of this, we have also on Page 6 of 108:24 10, these are -- this -- well, why don't you 108:25 describe what this is? 109:1 A. Just a projection of how much you think 109:2 you can sell.	03_13_18 combo final4.27 HUDNALL20.8.1
109:16 - 109:25	Hudnall, Janet 11-01-2013 (00:00:17) 109:16 Q. You thought you could grow 109:17 from 3 percent to 25 percent -- 109:18 A. Yes. 109:19 Q. -- market share, and that the units could 109:20 go from 3,000 in the first year to 41,000 in year	03_13_18 combo final4.29 HUDNALL20.8.2

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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	109:21 five, right?	
	109:22 A. Yes.	
	109:23 Q. In fact, you did -- actually did better	clear
	109:24 than that, didn't you?	
	109:25 A. Great. I don't know. I don't know.	
115:4 - 115:9	Hudnall, Janet 11-01-2013 (00:00:13)	03_13_18 combo final4.30
	115:4 Q. So you prepared the	
	115:5 document, you signed -- you sent it off to these	
	115:6 folks, and the people signed off on it, meaning	
	115:7 what?	
	115:8 A. Signing off means they have reviewed it	
	115:9 and approved it, or agree with it.	
115:24 - 116:1	Hudnall, Janet 11-01-2013 (00:00:05)	03_13_18 combo final4.31
	115:24 Q. And how were you involved in preparing for	
	115:25 the launch?	
	116:1 A. I -- I was the architect of the launch.	
120:25 - 121:14	Hudnall, Janet 11-01-2013 (00:00:28)	03_13_18 combo final4.32
	120:25 And there's other things that could	
	121:1 happen, with the vena cava being where it's	
	121:2 located, if this device isn't built as robustly and	
	121:3 as safely as possible, are there not?	
	121:4 A. Like what?	
	121:5 Q. Well, I don't know. You -- you don't	
	121:6 know?	
	121:7 A. You must have some sort of an answer in	
	121:8 mind when you're asking a question.	
	121:9 Q. Well, I was hoping you would -- you would	
	121:10 know what those are.	
	121:11 A. Well, why don't you -- why don't you tell	
	121:12 me, and I'll give you yes or no answers.	
	121:13 Q. You'd rather do it that way?	
	121:14 A. Yeah.	
127:11 - 127:19	Hudnall, Janet 11-01-2013 (00:00:14)	03_13_18 combo final4.33
	127:11 Q. As a marketer --	
	127:12 A. Yes.	
	127:13 Q. -- of a pharmaceutical or medical device?	
	127:14 A. Don't know anything about pharmaceuticals.	
	127:15 Q. Of a medical device, you need to know what	
	127:16 fair balance means, don't you?	
	127:17 A. I do.	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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127:21 - 127:22	<p>127:18 Q. And you -- and just give me your 127:19 description of fair balance?</p> <p>Hudnall, Janet 11-01-2013 (00:00:02)</p> <p>127:21 THE WITNESS: I -- why do I need to give 127:22 that to you?</p>	03_13_18 combo final4.34
129:6 - 129:9	<p>Hudnall, Janet 11-01-2013 (00:00:09)</p> <p>129:6 Q. BY MR. LOPEZ: My question is: What does 129:7 "fair balance" mean to you when it comes to 129:8 marketing a medical device? You don't know? 129:9 A. You -- I guess I don't. I guess I don't.</p>	03_13_18 combo final4.35
136:13 - 136:20	<p>Hudnall, Janet 11-01-2013 (00:00:27)</p> <p>136:13 Q. Did you ever receive any data during the 136:14 entire time that the Recovery was on the market 136:15 which revealed any statistics about how many -- of 136:16 how many patients were saved from a pulmonary 136:17 embolism going to their heart by having a Recovery 136:18 filter in them, any statistics? 136:19 A. That's theoretically the same number of 136:20 units that -- that were implanted.</p>	03_13_18 combo final4.36
137:24 - 138:24	<p>Hudnall, Janet 11-01-2013 (00:00:50)</p> <p>137:24 Q. if a doctor or anyone 137:25 were to ask you, well, okay, well, we have got a 138:1 number of these where the -- where there was a 138:2 thrombus. It hit the -- it hit the filter. The 138:3 filter didn't prevent it from going to the heart; 138:4 in fact, it took the filter with it and went to the 138:5 heart. 138:6 And then you said, "Well, how many have 138:7 you had where the thrombus went to the filter and 138:8 stopped?" 138:9 You wouldn't be able to give a number for 138:10 that, would you? 138:11 A. Nobody can, and we certainly couldn't. 138:12 Q. What do you mean "nobody can"? 138:13 A. How would you know that? 138:14 Q. Well, I don't know. I mean, how would 138:15 you -- you tell me. 138:16 A. Nobody can know that. 138:17 Q. How could -- 138:18 A. Unless you -- unless you take every</p>	03_13_18 combo final4.37

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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138:19	patient who has ever had a filter placed and you	
138:20	put realtime imaging on them, 24 hours a day, every	
138:21	single day, and see what's going on with any kind	
138:22	of thrombus that's forming in their legs and their	
138:23	hips and you see and you visualize it, there's no	
138:24	way to know that.	
139:19 - 139:23	Hudnall, Janet 11-01-2013 (00:00:16)	03_13_18 combo final4.38
139:19	that's not what I'm asking. I am asking you just	
139:20	pure data. There's no data that exists that shows	
139:21	that in a Recovery filter, there was a thrombus	
139:22	that was stopped by a Recovery or G2 filter from	
139:23	going beyond the filter?	
139:25 - 140:6	Hudnall, Janet 11-01-2013 (00:00:08)	03_13_18 combo final4.39
139:25	Q. BY MR. LOPEZ: Right?	
140:1	A. No one -- no one else, either.	
140:2	Q. So is the answer am I right?	
140:3	A. Are you right?	
140:4	Q. Yeah.	
140:5	A. If you need to hear that, yes, you are	
140:6	right.	
143:4 - 143:21	Hudnall, Janet 11-01-2013 (00:00:53)	03_13_18 combo final4.41
143:4	Q. Caval trapping and caval patency; that was	_1_HUDNALL21.1.1
143:5	a feature that you were selling as a benefit of the	
143:6	product?	
143:7	A. Yes.	
143:8	Q. what's the significance of	HUDNALL21.1.4
143:9	self-centering?	
143:10	A. So the device is a conical device that has	
143:11	a single layer coming in from the below. Just	
143:12	because of the mechanical forces, it has to tilt.	
143:13	Because this device had a delivery system that had	
143:14	some specific features on it, had a better chance	
143:15	of deploying in a centered manner upon deployment.	
143:16	Q. And -- and centering is important because	clear
143:17	tilting could cause some problems in a filter,	
143:18	right?	
143:19	A. I think they later found out -- well,	
143:20	theoretically, yes. A -- a single-level filter	
143:21	which tilts could potentially have issues.	
154:8 - 154:10	Hudnall, Janet 11-01-2013 (00:00:03)	03_13_18 combo final4.42

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	154:8 Q. Then the next one is Exhibit 22.	_1_HUDNALL22.1
	154:9 (Reporter marked Exhibit No. 22 for	
	154:10 identification.)	
154:18 - 155:19	Hudnall, Janet 11-01-2013 (00:01:11)	03_13_18 combo final4.43
	154:18 Q. what	
	154:19 would you call this piece?	
	154:20 A. It's the same thing. It's a screen shot	
	154:21 of a web page.	clear
	154:22 Q. Okay. And again, this would contain the	
	154:23 same information that you would have in a brochure	
	154:24 that you would leave with a doctor or what you	
	154:25 would put in a journal?	
	155:1 A. The journal wouldn't contain this much	
	155:2 information, but yes, it would be in a brochure.	
	155:3 Q. Okay. So this is the -- by the way, the	
	155:4 G2 is just the next -- they call it a G2 because	
	155:5 it's the next generation of Recovery, correct?	
	155:6 A. Correct.	
	155:7 Q. And according to this marketing piece, one	
	155:8 of the advantages -- some of the advantages of the	HUDNALL22.1.2
	155:9 G2 were increased migration resistance, improved	
	155:10 centering, and enhanced fracture resistance.	
	155:11 A. Yes.	
	155:12 Q. Compared to what?	
	155:13 A. Compared to the previous generation.	
	155:14 Q. Okay. And again, you have this comment	_1_HUDNALL22.1.1
	155:15 about secure fixation?	
	155:16 A. Yes.	clear
	155:17 Q. And was it true that the G2 was designed	
	155:18 because of issues with migration resistance,	
	155:19 centering issues, and some fractures?	
155:21 - 156:1	Hudnall, Janet 11-01-2013 (00:00:09)	03_13_18 combo final4.44
	155:21 THE WITNESS: It's an improvement to the	
	155:22 previous device, yes.	
	155:23 Q. BY MR. LOPEZ: But it was designed	
	155:24 specifically because of migration resistance	
	155:25 issues, centering issues, and fracture issues with	
	156:1 the recovery?	
156:3 - 156:5	Hudnall, Janet 11-01-2013 (00:00:03)	03_13_18 combo final4.45
	156:3 THE WITNESS: Because of?	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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156:4	Q. BY MR. LOPEZ: Yeah.	
156:5	A. Yeah, you could call it that.	
156:9 - 156:13	Hudnall, Janet 11-01-2013 (00:00:22)	03_13_18 combo final4.46
156:9	Then the next document is -- I am going to	
156:10	give you this as one big document, although it	_1_HUDNALL23.1
156:11	appears to be more than one document, but they are	
156:12	consecutively Bates stamped, and this is going to	
156:13	be -- am I on 23?	
157:13 - 157:18	Hudnall, Janet 11-01-2013 (00:00:17)	03_13_18 combo final4.47
157:13	Q. And however, the messages are -- with	HUDNALL23.1.2
157:14	respect to migration resistance, improved	
157:15	centering, and fracture resistance are the same,	
157:16	right?	
157:17	Do you see that?	
157:18	A. Yes.	
166:6 - 166:11	Hudnall, Janet 11-01-2013 (00:00:11)	03_13_18 combo final4.48
166:6	Q. If it did not have increased migration	clear
166:7	resistance when compared to your competitive	
166:8	products and you had data to suggest that, would	
166:9	that be misleading?	
166:10	A. If we had data to suggest that it would be	
166:11	misleading, yes.	
166:12 - 166:14	Hudnall, Janet 11-01-2013 (00:00:07)	03_13_18 combo final4.49
166:12	Q. So if the G2 was cleared for	
166:13	retrievability indication in January of 2008,	
166:14	this -- this is -- this would be your piece, right?	
166:17 - 166:17	Hudnall, Janet 11-01-2013 (00:00:01)	03_13_18 combo final4.86
166:17	THE WITNESS: Yes.	
178:4 - 178:5	Hudnall, Janet 11-01-2013 (00:00:02)	03_13_18 combo final4.50
178:4	MR. LOPEZ: What number are we on, please?	
178:5	THE REPORTER: 24.	
178:9 - 178:19	Hudnall, Janet 11-01-2013 (00:00:36)	03_13_18 combo final4.51
178:9	Q. BY MR. LOPEZ: This is a February 27,	HUNDNALL 24RAUCH.1.1
178:10	2004, email from David Rauch to Janet Hudnall. Did	
178:11	you see this before the deposition?	
178:12	A. Yes.	
178:13	Q. Who is David Rauch?	HUNDNALL 24RAUCH.1
178:14	A. He, I think, at the time was a -- he used	
178:15	to be a sales rep. I think at the time he was --	
178:16	was a sales trainer.	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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178:17 Q. And then this was -- the subject here is

HUNDNALL 24RAUCH.1.2

178:18 "Case for caval centering"?

178:19 A. Uh-huh.

179:1 - 180:15

Hudnall, Janet 11-01-2013 (00:01:22)

03_13_18 combo final4.52

179:1 He's commenting on a training piece.

179:2 Would that be one of your training pieces, right?

179:3 A. Maybe.

HUNDNALL 24RAUCH.1.3

179:4 Q. "Having said that, however, I must

179:5 strongly caution against emphasizing Recovery's

179:6 ability to center in the cava to the point where it

179:7 is the focus of product positioning."

179:8 A. Uh-huh.

179:9 Q. "We knew very little about long-term

179:10 clinical performance of this" -- "of this device

179:11 when we launched it. After a year of

179:12 commercialization, there are still many questions

179:13 that need to be answered."

179:14 A. Uh-huh.

179:15 Q. "One thing that we do know, however, is

179:16 that Recovery does not always stay centered in the

179:17 cava."

179:18 A. Uh-huh.

179:19 Q. Right?

179:20 A. Yep.

HUNDNALL 24RAUCH.1.4

179:21 Q. And that even says here at the bottom, "I

179:22 think for a piece like this, it's critical to

179:23 clearly reference the entire body of the text so

179:24 that the reader can differentiate between what is

179:25 documented in the literature and what is

180:1 anecdotal/opinion."

180:2 A. Uh-huh.

180:3 Q. And then you answered -- I'm sorry,

180:4 then -- that was -- no, actually, that was from you

180:5 to David?

180:6 A. Right.

HUNDNALL 24RAUCH.1.5

180:7 Q. And then you wrote back to David, "Thank

180:8 you for your valuable feedback. You are right.

180:9 Now that we have more experience with Recovery, the

180:10 positioning and tilt resistance should probably be

180:11 downplayed."

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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	180:12 A. Uh-huh.	
	180:13 Q. You saw this before the deposition; you	clear
	180:14 knew I was going to probably ask you questions	
	180:15 about this, right?	
180:17 - 180:17	Hudnall, Janet 11-01-2013 (00:00:01)	03_13_18 combo final4.53
	180:17 THE WITNESS: Possibly.	
181:24 - 182:7	Hudnall, Janet 11-01-2013 (00:00:23)	03_13_18 combo final4.54
	181:24 Q. Okay. "Should probably be played down."	
	181:25 So if -- if a doctor were to ask Mr. Rauch, or	
	182:1 anybody, including you, "Tell me about the tilt	
	182:2 resistance of your product," was your instruction	
	182:3 to play that down?	
	182:4 A. No.	
	182:5 Q. Okay. What was your instruction?	
	182:6 A. I don't remember what my instruction would	
	182:7 have been.	
184:2 - 184:17	Hudnall, Janet 11-01-2013 (00:00:29)	03_13_18 combo final4.55
	184:2 You're	
	184:3 saying to Dave, that, in fact, physicians will	HUNDNALL 24RAUCH.1.6
	184:4 often find that it's tilted quite a bit when they	
	184:5 go to retrieve it, even though it seemed perfectly	
	184:6 centered upon deployment, right?	
	184:7 A. Okay.	
	184:8 Q. How did you know that?	
	184:9 A. I guess we -- I guess people were calling	
	184:10 and saying that that's what they saw when they went	
	184:11 in to retrieve it.	
	184:12 Q. And "quite a bit" means what to you?	clear
	184:13 A. "Quite a bit" is -- I don't know. At the	
	184:14 time --	
	184:15 Q. More than you expected?	
	184:16 (Speaking simultaneously.)	
	184:17 THE WITNESS: Yeah, sure.	
185:10 - 185:24	Hudnall, Janet 11-01-2013 (00:00:41)	03_13_18 combo final4.56
	185:10 Q. The question is: What did you mean when	
	185:11 you said that if you sell the device solely on this	
	185:12 feature, it could set the sales rep up for some	
	185:13 uncomfortable situations in the long run?	
	185:14 A. Oh, sure. Okay. Okay. So we have had	
	185:15 some people say that when they go in to retrieve	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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185:16 it, it looks tilted. So if -- apparently, Dave
 185:17 created this document that talks all about how it
 185:18 stays centered or it is centered, whatever it was,
 185:19 and it was full of opinions, it sounds like. Okay?
 185:20 So if a sales rep were to go in and sell based on
 185:21 that approach, then he's going to have the hard
 185:22 time passing the red-face test later on when the
 185:23 physician goes in to retrieve it and it looks
 185:24 tilted, because he's made these promises.

186:18 - 187:2

Hudnall, Janet 11-01-2013 (00:00:29)

03_13_18 combo final4.57

186:18 Q. If, in fact, you had an unexpected number
 186:19 of tilting of this device, even after properly was
 186:20 deployed and centering, and you knew that tilting
 186:21 led to other evils with respect to the device,
 186:22 including migration, perforation, and fracture,
 186:23 isn't that something that doctors ought to know?
 186:24 A. I did not know that at the time.

186:25 Q. But isn't that something that doctors
 187:1 ought to know?

187:2 A. Sure, sure.

187:10 - 187:14

Hudnall, Janet 11-01-2013 (00:00:08)

03_13_18 combo final4.58

187:10 Q. BY MR. LOPEZ: No one told you that? No
 187:11 one told you that tilting --

187:12 A. I don't have to be told things to know,
 187:13 first of all, but no, we never concluded that it
 187:14 leads to these evils.

269:25 - 270:5

Hudnall, Janet 11-01-2013 (00:00:20)

03_13_18 combo final4.59

269:25 Q. No. 5, "Address the physician's concerns
 270:1 He wrote "The

270:2 Recovery filter has been tested to verify that it
 270:3 meets the migration resistance parameters that have
 270:4 been used for the Simon Nitinol filter."

270:5 A. Okay.

273:3 - 274:4

Hudnall, Janet 11-01-2013 (00:01:03)

03_13_18 combo final4.60

273:3 Q. And there's a question here, "What is the
 273:4 migration rate for Recovery?"

273:5 A. Okay.

273:6 Q. Was that a question? Why is that question
 273:7 there? Because you anticipate those line of
 273:8 questions from the marketplace?

HUDNALL29.1
HUDNALL29.2.1

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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273:9 A. Probably.

273:10 Q. And your answer was, "It is very difficult
273:11 to determine actual rates because it is impossible
273:12 to know the exact number of filters implanted, not
273:13 only for Recovery, but for all commercially
273:14 available filters," right?

273:15 A. That's true.

273:16 Q. "The only way to come close to comparing
273:17 apples to apples is to review the number of
273:18 reported incidents to the FDA MAUDE database,"
273:19 right?

273:20 A. Okay.

273:21 Q. I asked you earlier about this. You're
273:22 saying here that the only thing that the world has
273:23 available to get any idea about how devices compare
273:24 to each other from the standpoint of risk and
273:25 complications is the MAUDE database?

274:1 A. Okay.

274:2 Q. Okay. That's what you're saying in this
274:3 memo, best you got, right?

274:4 A. I guess so.

296:9 - 296:19

Hudnall, Janet 11-01-2013 (00:00:25)

296:9 Let's look at the next one: "Is Recovery
296:10 a safe device?" And you told them to answer it
296:11 this way: "The Recovery filter was rigorously
296:12 tested for all physical performance -- performance
296:13 characteristics according to our established tested
296:14 methods and protocols. For all performance
296:15 criteria, the Recovery performed as well as or
296:16 better than the Simon Nitinol filter, the predicate
296:17 device."

296:18 That's what you wanted them to tell

296:19 people, right?

296:21 - 297:7

Hudnall, Janet 11-01-2013 (00:00:22)

296:21 THE WITNESS: That was the truth.

296:22 Q. BY MR. LOPEZ: Okay. Now, "As for
296:23 migration resistance, we first determined the
296:24 pressure graded," and you went on to talk about
296:25 what you did to determine migration resistance,
297:1 correct?

HUDNALL29.3.2

HUDNALL29.3.3

03_13_18 combo final4.61

HUDNALL29.4.1

03_13_18 combo final4.62

HUDNALL29.4.3

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	297:2 A. Uh-huh.	
	297:3 Q. Is that right?	
	297:4 A. Yes.	
	297:5 Q. So you wanted the world to believe that	HUDNALL29.4
	297:6 the Simon Nitinol -- the Recovery filter actually	
	297:7 performed better than the Simon Nitinol filter?	
297:9 - 297:18	Hudnall, Janet 11-01-2013 (00:00:23)	03_13_18 combo final4.63
	297:9 Q. BY MR. LOPEZ: Effectiveness and safety?	clear
	297:10 A. I wanted the world to know exactly what it	
	297:11 says here.	
	297:12 Q. Okay. But isn't the takeaway message from	
	297:13 whatever is said there to the listener, this	
	297:14 product is outperforming the Simon Nitinol filter	
	297:15 from a safety and efficacy standpoint? You don't	
	297:16 think that's --	
	297:17 A. The takeaway message is exactly what's	
	297:18 written.	
297:19 - 298:11	Hudnall, Janet 11-01-2013 (00:00:38)	03_13_18 combo final4.64
	297:19 Q. Well, I am asking you as a marketer when	HUDNALL29.4.4
	297:20 you say that these things, that the Recovery	
	297:21 performed as well or better than the Simon Nitinol	
	297:22 filter, aren't you telling the world that the	
	297:23 Recovery filter is safer and more effective than	
	297:24 the Simon Nitinol filter?	
	297:25 A. No.	
	298:1 Q. You don't think so?	
	298:2 A. No. I wrote it.	
	298:3 Q. I know, but this is meant --	
	298:4 A. This is at face value. Take this at face	
	298:5 value.	
	298:6 Q. I am not going to take it at face value.	
	298:7 I am asking you as a marketer, isn't your message:	
	298:8 Our Recovery filter is safer and more effective	
	298:9 than the Simon Nitinol filter?	
	298:10 A. I was asking the reader to take this at	
	298:11 face value.	
316:9 - 316:16	Hudnall, Janet 11-01-2013 (00:00:24)	03_13_18 combo final4.65
	316:9 Q. If you look at it compared to the Simon	clear
	316:10 Nitinol filter, at least from a percentage-basis,	
	316:11 there's almost a 20 -- what is that -- almost a	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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316:12	2500 percent increase in migrations between the	
316:13	Recovery and the Simon Nitinol filter?	
316:14	A. Okay.	
316:15	Q. Do you agree with me?	
316:16	A. I agree with you on that.	
316:19 - 317:9	Hudnall, Janet 11-01-2013 (00:00:28)	03_13_18 combo final4.66
316:19	Q. BY MR. LOPEZ: Do you think that's	
316:20	equivalent?	
316:21	A. I have to go back to risk/benefit.	
316:22	Q. I am asking you from just a pure	
316:23	standpoint of that being --	
316:24	A. Just looking at numbers, no, it is not	
316:25	comparable.	
317:1	Q. Just looking at it from pure safety	
317:2	standpoint?	
317:3	A. Looking at purely these numbers, no.	
317:4	Q. From a pure safety standpoint?	
317:5	A. Looking at a pure numbers standpoint, it	
317:6	looks like they are not comparable.	
317:7	Q. It looks like the Recovery from a	
317:8	migration standpoint is more dangerous than the	
317:9	Simon Nitinol filter?	
317:11 - 317:13	Hudnall, Janet 11-01-2013 (00:00:05)	03_13_18 combo final4.67
317:11	THE WITNESS: Looking at these numbers,	
317:12	purely at these numbers, I am not going to make	
317:13	judgment, they are not comparable.	
358:5 - 358:15	Hudnall, Janet 11-01-2013 (00:00:34)	03_13_18 combo final4.68
358:5	Q. You were asked at some	
358:6	point in time to deal with another FAQ regarding	
358:7	the G2 filter, and one of the questions was what	
358:8	other databases are out there to track medical	
358:9	device-related injuries, and you recall that your	
358:10	answer was unfortunately MAUDE is the only source	
358:11	of this type of information?	
358:12	A. Yes.	
358:13	Q. It was the best information the company	
358:14	had?	
358:15	A. It's the only information.	
358:24 - 359:4	Hudnall, Janet 11-01-2013 (00:00:33)	03_13_18 combo final4.69
358:24	Q. Then when you compare the number of	

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359:6 - 359:13	<p>358:25 fatalities to any other filter that was on the</p> <p>359:1 market, fatalities, people dying, I mean, there's</p> <p>359:2 nothing comparable about that at all, is there?</p> <p>359:3 The Recovery filter was way worse than the others;</p> <p>359:4 wouldn't you agree?</p> <p>Hudnall, Janet 11-01-2013 (00:00:31)</p> <p>359:6 THE WITNESS: Okay.</p> <p>359:7 Q. BY MR. LOPEZ: Wouldn't you agree?</p> <p>359:8 A. Based on these numbers, yes.</p> <p>359:9 Q. And the number of migrations significantly</p> <p>359:10 different, not comparable, not the same, .13</p> <p>359:11 percent migration versus the Simon Nitinol filter,</p> <p>359:12 I don't know, what's that about 15,000 percent</p> <p>359:13 different?</p>	03_13_18 combo final4.70
359:16 - 360:8	<p>Hudnall, Janet 11-01-2013 (00:00:43)</p> <p>359:16 Q. BY MR. LOPEZ: Isn't that just a dramatic</p> <p>359:17 difference when you compare the Recovery to the</p> <p>359:18 Simon Nitinol filter?</p> <p>359:19</p> <p>359:20 Q. BY MR. LOPEZ: When it comes to migration?</p> <p>359:21 A. Based on that information, yes.</p> <p>359:22 Q. This is based on information from actual</p> <p>359:23 data that the company had?</p> <p>359:24 A. Based on actual data the company had, yes.</p> <p>359:25 Q. And filter embolization, that means the</p> <p>360:1 filter is going somewhere distant to another part</p> <p>360:2 of the body, right?</p> <p>360:3 A. Okay.</p> <p>360:4 Q. Look at the difference between the</p> <p>360:5 Recovery filter and the Simon Nitinol filter for</p> <p>360:6 embolizations.</p> <p>360:7 A. Is there a question there?</p> <p>360:8 Q. Isn't that a dramatic difference?</p>	03_13_18 combo final4.72
360:10 - 360:12	<p>Hudnall, Janet 11-01-2013 (00:00:05)</p> <p>360:10 THE WITNESS: Yes.</p> <p>360:11 Q. BY MR. LOPEZ: That's like 4,000 percent</p> <p>360:12 difference?</p>	03_13_18 combo final4.73
360:14 - 360:14	<p>Hudnall, Janet 11-01-2013 (00:00:00)</p> <p>360:14 THE WITNESS: Okay.</p>	03_13_18 combo final4.74
361:8 - 361:11	<p>Hudnall, Janet 11-01-2013 (00:00:10)</p>	03_13_18 combo final4.75

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361:8	The	
361:9	differences in these significant complications that	
361:10	could lead to death are dramatic?	
361:11	A. Okay.	
361:13 - 361:13	Hudnall, Janet 11-01-2013 (00:00:00)	03_13_18 combo final4.76
361:13	Q. BY MR. LOPEZ: Would you agree with me,	
361:17 - 361:22	Hudnall, Janet 11-01-2013 (00:00:10)	03_13_18 combo final4.77
361:17	THE WITNESS: They are higher, yes.	
361:18	Q. BY MR. LOPEZ: If you had to choose	
361:19	between "comparable" or "dramatic," which word	
361:20	would you use?	
361:21	A. I wouldn't use either. I would say it is	
361:22	higher.	
373:16 - 373:20	Hudnall, Janet 11-01-2013 (00:00:15)	03_13_18 combo final4.78
373:16	it's in	
373:17	February of 2005. So we have gone backwards in	HUDNALL 34 236_BPV.1.1
373:18	time a little bit, at least based on the documents	
373:19	we have been looking at, who is Charlie Simpson?	
373:20	A. He was one of the R&D directors.	
375:2 - 375:8	Hudnall, Janet 11-01-2013 (00:00:18)	03_13_18 combo final4.79
375:2	Q. Charlie says that "Mary Proctor	HUDNALL 34 236_BPV.1.2
375:3	presented an evaluation of filter-related filings	
375:4	from the MAUDE database as well as her opinion of	
375:5	the optimum design features for a vena cava	
375:6	filter."	
375:7	Do you see that?	
375:8	A. I do.	
376:17 - 377:22	Hudnall, Janet 11-01-2013 (00:01:27)	03_13_18 combo final4.80
376:17	Q. Here's a situation where she's looking	clear
376:18	at the MAUDE database, right?	
376:19	A. Okay.	
376:20	Q. Because it is the only thing we had?	
376:21	A. Right.	
376:22	Q. "The number of MAUDE reports of migration	HUDNALL 34 236_BPV.1.3
376:23	and penetration associated with the Recovery filter	
376:24	are concerning."	
376:25	A. Okay.	
377:1	Q. "During her presentation she said that the	
377:2	Recovery had the highest incidence of death from	
377:3	June 2003 to June 2004, ten for Recovery, one for	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

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	377:4 all others. She stated that she believed the	
	377:5 problems are associated with a weak attachment."	
	377:6 Did I read that correctly?	
	377:7 A. You seem to have.	clear
	377:8 Q. Okay. And she was presenting this to a	
	377:9 bunch of doctors at a forum?	
	377:10 A. I don't know who the audience was.	
	377:11 Q. Okay. And then you replied to her, right?	
	377:12 A. To her, no.	
	377:13 Q. I'm sorry. You replied to Charlie. I beg	
	377:14 your pardon.	
	377:15 A. Okay.	
	377:16 Q. And you wrote Charlie, "Thank you so much	HUDNALL 34 236_BPV.1.4
	377:17 for the information. This definitely helps me	
	377:18 anticipate some questions and plan our rebuttals.	
	377:19 Thanks for keeping your eyes and ears open."	
	377:20 Did I read that correctly?	
	377:21 A. You did.	clear
	377:22 Q. What's there to rebut?	
377:25 - 377:25	Hudnall, Janet 11-01-2013 (00:00:01)	03_13_18 combo final4.82
	377:25 THE WITNESS: Facts.	
380:3 - 380:7	Hudnall, Janet 11-01-2013 (00:00:12)	03_13_18 combo final4.83
	380:3 Q. Well, but we knew -- we	
	380:4 know that there was -- with respect to the G2 was	
	380:5 being designed to have a greater adherence and	
	380:6 attachment to the cava wall?	
	380:7 A. And still allow retrievability, yes.	
380:11 - 380:20	Hudnall, Janet 11-01-2013 (00:00:23)	03_13_18 combo final4.84
	380:11 Q. But to still allow retrievability	
	380:12 but still have the same protection against	
	380:13 migration that a permanent device would have?	
	380:14 A. Yes, yes.	
	380:15 Q. And the reason that this thing was	
	380:16 migrating and causing deaths is because the	HUDNALL 34 236_BPV.1.5
	380:17 Recovery did, in fact, quote, have a weak	clear
	380:18 attachment, end quote, that didn't allow it to stop	
	380:19 thrombi from dislodging it and sending it to the	
	380:20 heart, true?	
380:22 - 380:23	Hudnall, Janet 11-01-2013 (00:00:04)	03_13_18 combo final4.85
	380:22 THE WITNESS: Very, very simplified, yeah,	

03_13_18 combo final4-Hudnall 11-01-13 Booker Depo Designations final4

Page/Line

Source

ID

380:23 I guess it is true. I don't know.

Plaintiffs Designations = 00:25:31

DefenseDesignations = 00:03:47

P & D Designations = 00:00:18

Total Time = 00:29:36

Documents Shown

_1_HUDNALL21

_1_HUDNALL22

_1_HUDNALL23

HUDNALL 34 236_BPV

HUDNALL20

HUDNALL21

HUDNALL22

HUDNALL23

HUDNALL29

HUNDNALL 24RAUCH

EXHIBIT D

Designation Run Report

Cohen 01-25-17 Booker Depo Designations Final 2

Cohen, Gary 01-25-2017

Plaintiffs Designations 00:02:50

DefenseDesignations 00:01:04

Total Time 00:03:54



03_20_18 Combo final 2-Cohen 01-25-17 Booker Depo Designations Final 2

Page/Line	Source	ID
8:13 - 8:16	Cohen, Gary 01-25-2017 (00:00:09) 8:13 if you can tell the jury your name and your current 8:14 occupation, affiliation. 8:15 A. Gary Cohen, I'm an interventional 8:16 radiologist, Temple University Hospital.	03_20_18 Combo final 2.1
30:19 - 30:22	Cohen, Gary 01-25-2017 (00:00:10) 30:19 Did you think in 2003 that Recovery was 30:20 going to be a game changer? 30:21 A. I thought that a optional filter could 30:22 be a game changer, yes.	03_20_18 Combo final 2.2
31:17 - 31:22	Cohen, Gary 01-25-2017 (00:00:20) 31:17 Q. What were your concerns about the 31:18 Recovery when you stopped using it at the end of 2004? 31:19 A. We had two incredibly unfortunate, 31:20 devastating outcomes and did not know exactly why we 31:21 had them, and I didn't feel we should continue to use a 31:22 product due to internal forces and those outcomes.	03_20_18 Combo final 2.3
46:18 - 47:10	Cohen, Gary 01-25-2017 (00:01:04) 46:18 Q. This is Exhibit 736. This is a monthly 46:19 report of Bard, again, Janet Hudnall, and it talks 46:20 about the business impact, and it gives a lot of 46:21 details about the sale of various devices, including 46:22 the Recovery on the front page, but I want to direct 46:23 your attention to the second page under "Recovery." So 46:24 now this is April of '04. 47:1 It says as of this time Bard had trained 47:2 136 different doctors on the Recovery. And then it 47:3 mentions here under "Complaints/QC Hold," Recovery was 47:4 placed on a QC hold, quality control hold, on 47:5 April 13th after receiving a report of a fatal 47:6 migration and then for privacy it protects the name. 47:7 Were you aware that there was a quality 47:8 control hold on April 13th of 2004 because of a fatal 47:9 migration? 47:10 A. I was not.	03_20_18 Combo final 2.4 ...1_G COHEN 736.1.2 ...1_G COHEN 736.1.1 ...1_G COHEN 736.2.2 ...1_G COHEN 736.2.3 ...1_G COHEN 736.2.4 clear
68:12 - 68:18	Cohen, Gary 01-25-2017 (00:00:12) 68:12 Q. Well, ultimately, the reason why 68:13 you stopped using the device that year was because of 68:14 two fatalities here at Temple, correct? 68:15 A. Correct.	03_20_18 Combo final 2.5

Page/Line	Source	ID
71:12 - 71:20	<p>68:16 Q. And they were two migration related</p> <p>68:17 fatalities, correct?</p> <p>68:18 A. Correct.</p> <p>Cohen, Gary 01-25-2017 (00:00:16)</p> <p>71:12 Q. In your practice, two fatalities here at</p> <p>71:13 Temple University Medical Center, they caused you to</p> <p>71:14 have great concern about the safety and efficacy of the</p> <p>71:15 device in your practice, correct?</p> <p>71:16 A. They caused me great concern, yes,</p> <p>71:17 absolutely.</p> <p>71:18 Q. And it actually caused you to stop using</p> <p>71:19 the device, correct?</p> <p>71:20 A. Yes.</p>	03_20_18 Combo final 2.6
123:1 - 123:11	<p>Cohen, Gary 01-25-2017 (00:00:24)</p> <p>123:1 Q. You would agree with me that the memo</p> <p>123:2 that you sent to Bard was prepared by the folks at</p> <p>123:3 Temple doing investigations about migratory deaths of</p> <p>123:4 the Recovery?</p> <p>123:5 A. By Temple risk management, yes.</p> <p>123:6 Q. So at least Temple, this hospital --</p> <p>123:7 A. Correct.</p> <p>123:8 Q. -- believed that as of August of 2004,</p> <p>123:9 it researched and found six reported deaths related to</p> <p>123:10 the migration of the Recovery, correct?</p> <p>123:11 A. Yes, that's correct.</p>	03_20_18 Combo final 2.11
129:8 - 129:11	<p>Cohen, Gary 01-25-2017 (00:00:10)</p> <p>129:8 Q. That's the only issue. I'm asking, do</p> <p>129:9 you -- in advising your patients, do you want complete</p> <p>129:10 and accurate information about the device?</p> <p>129:11 A. 100%.</p>	03_20_18 Combo final 2.12
137:15 - 137:18	<p>Cohen, Gary 01-25-2017 (00:00:17)</p> <p>137:15 Q. So to that extent, and only that extent,</p> <p>137:16 the Simon Nitinol filter was a safer product for your</p> <p>137:17 patients, at least with respect or only with respect to</p> <p>137:18 the issue of potential fatalities from migration?</p>	03_20_18 Combo final 2.13
137:21 - 137:22	<p>Cohen, Gary 01-25-2017 (00:00:04)</p> <p>137:21 Q. At this time frame?</p> <p>137:22 A. Yes.</p>	03_20_18 Combo final 2.14
152:17 - 152:21	<p>Cohen, Gary 01-25-2017 (00:00:22)</p> <p>152:17 Q. Okay. If Bard's documents show that on</p>	03_20_18 Combo final 2.15

Page/Line	Source	ID
152:18	the first migration that you had that you spoke to John	
152:19	Ammerman about that three people from Bard came to see	
152:20	you, Rob Carr, Cindi Walcott and Hudnall, do you have	
152:21	any recollection of that meeting?	
153:3 - 153:9	Cohen, Gary 01-25-2017 (00:00:20)	03_20_18 Combo final 2.16
153:3	THE WITNESS: I think I alluded to this	
153:4	that there is sort of this merging of time	
153:5	frame and emotion during that time frame.	
153:6	There certainly was at least once where Bard	
153:7	I don't specifically remember who	
153:8	came, but it makes sense to me that it would	
153:9	have been two or three people.	
<hr/>		
Plaintiffs Designations = 00:02:50		
DefenseDesignations = 00:01:04		
Total Time = 00:03:54		
Documents Shown		
_1_G COHEN 736		
<hr/>		
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EXHIBIT E

Designation Run Report

D'Ayala 03-21-17 Booker Depo Designation Final3.1

D, ayala 03-21-2017

Plaintiffs Designations 00:23:55

Defense Designations 00:16:37

Plaintiffs and defense Designations 00:00:50

Total Time 00:41:22



03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
10:12 - 10:17	D, ayala 03-21-2017 (00:00:09) 10:12 Doctor, could you state your name, 10:13 please? 10:14 A. Marcus D'Ayala. 10:15 Q. And what do you do, sir? 10:16 A. I'm a vascular surgeon in clinical 10:17 practice in Brooklyn, New York.	03_20_18 combo final3_1.1
13:9 - 13:19	D, ayala 03-21-2017 (00:00:31) 13:9 Q. Doctor, I represent Sherr-Una 13:10 Booker. She was a patient of yours back in 2007. 13:11 You, at that time, implanted a G2, Bard G2 IVC 13:12 filter. 13:13 I suspect you do not recall her 13:14 personally? 13:15 A. I do not. 13:16 Q. Have you had a chance to look at the 13:17 records, your records, of the implant and the 13:18 procedure that took place back in 2007? 13:19 A. I have.	03_20_18 combo final3_1.2
15:18 - 15:25	D, ayala 03-21-2017 (00:00:24) 15:18 Q. Today I'm here to ask you, really, 15:19 about three areas of inquiry; your treatment of Ms. 15:20 Booker, the decision to use the G2 filter, and then 15:21 what warnings you had, prior to implanting the 15:22 filter, about the risks and the benefit of the G2 15:23 filter. 15:24 Do you understand those three areas? 15:25 A. Yes.	03_20_18 combo final3_1.3
20:18 - 20:25	D, ayala 03-21-2017 (00:00:19) 20:18 Is it fair to say before you use any 20:19 medical device, the benefits have to outweigh the 20:20 risk of that device; is that a fair statement? 20:21 A. Yes. 20:22 Q. And that's how you practice medicine? 20:23 A. Yes. 20:24 Q. You look at benefits versus risks? 20:25 A. Yes.	03_20_18 combo final3_1.4
21:9 - 21:13	D, ayala 03-21-2017 (00:00:08) 21:9 Q. If there are significant risks, you 21:10 need to give informed consent to your patients if	03_20_18 combo final3_1.5

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
21:21 - 22:5	<p>21:11 there's potential for a serious injury or death, 21:12 correct? 21:13 A. Yes. D, ayala 03-21-2017 (00:00:27) 21:21 Q. Let me ask you about the 21:22 frequency of risk, and that is, the risk of serious 21:23 injury or death. 21:24 Is it important to you, as a treating 21:25 doctor that implants devices in a patient, what the 22:1 frequency of that risk is, whether it's one in a 22:2 million or one in ten? Is that an important -- is 22:3 that important information for you in determining 22:4 the risk versus benefit analysis? 22:5 A. Yes.</p>	03_20_18 combo final3_1.6
23:2 - 23:5	<p>D, ayala 03-21-2017 (00:00:10) 23:2 Is it important to you, as a 23:3 clinician that implants medical devices, to know the 23:4 frequency of which a device fails? 23:5 A. Yes.</p>	03_20_18 combo final3_1.7
23:15 - 23:24	<p>D, ayala 03-21-2017 (00:00:30) 23:15 Q. What about the risk of 23:16 serious injury, that is, the severity of the injury? 23:17 Is that also important for you to know, when doing a 23:18 risk/benefit analysis, whether you use a product or 23:19 not? 23:20 A. Yes. 23:21 Q. And those two individual points of 23:22 analysis, that is, frequency and severity of adverse 23:23 events, both of those are used in your prescribing 23:24 decisions?</p>	03_20_18 combo final3_1.8
24:1 - 24:5	<p>D, ayala 03-21-2017 (00:00:13) 24:1 THE WITNESS: Yes. 24:2 BY MR. MATTHEWS: 24:3 Q. Doctor, you only saw Ms. Booker in 24:4 June of 2007; is that correct? 24:5 A. Yes.</p>	03_20_18 combo final3_1.9
26:7 - 27:12	<p>D, ayala 03-21-2017 (00:01:50) 26:7 Q. So oftentimes, you'll treat a patient 26:8 and implant a filter, as an example, or a stent, and 26:9 that may be the only time that you see that patient?</p>	03_20_18 combo final3_1.10

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line

Source

ID

26:10 A. Yes, but that's not the norm.

26:11 Q. It's not the norm.

26:12 That's what happened with Ms. Booker,

26:13 though, correct?

26:14 A. I'm not entirely sure. What I would

26:15 say, that is customary for me is to see a patient

26:16 before a procedure, make an assessment regarding

26:17 whether or not that procedure is necessary, and

26:18 that, as you alluded to, typically involves a

26:19 complex risk/benefit analysis.

26:20 And there are many factors that come

26:21 into play when we make those risk/benefit analyses,

26:22 and they include things like the natural history of

26:23 their disease process, their age, their

26:24 comorbidities and their life expectancy, the

26:25 proposed risks of whatever intervention we have or

27:1 are planning for them and so on.

27:2 So my practice is such that I will

27:3 see somebody before, make an assessment as to what

27:4 is best, discuss treatment options with them, move

27:5 forward if a procedure is required, and then see

27:6 them, typically within a day afterwards to make sure

27:7 that there were no complications as a result of our

27:8 procedure.

27:9 It's also customary for us to -- for

27:10 me, at least, to ask my patients to come back for

27:11 follow-up visits, at least one, within 30 days of

27:12 surgery or discharge from hospital.

29:9 - 29:12

D, ayala 03-21-2017 (00:00:11)

03_20_18 combo final3_1.11

29:9 Q. Back in 2007 when you were implanting

29:10 in particular the G2, the G2 had only been cleared

29:11 for permanent implantation; is that correct?

29:12 A. Correct.

29:25 - 30:6

D, ayala 03-21-2017 (00:00:21)

03_20_18 combo final3_1.12

29:25 Can you tell the jury when you first

30:1 started using inferior vena cava filters, IVC

30:2 filters?

30:3 A. Sure. During my vascular training.

30:4 Q. What year was that?

30:5 A. That would have been at the Mount

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
31:13 - 31:16	<p>30:6 Sinai Hospital in '97, '98.</p> <p>D, ayala 03-21-2017 (00:00:07)</p> <p>31:13 Q. You said you moved away from the Bard</p> <p>31:14 filter because of problems associated with it,</p> <p>31:15 correct?</p> <p>31:16 A. Yes.</p>	03_20_18 combo final3_1.13
31:19 - 32:1	<p>D, ayala 03-21-2017 (00:00:22)</p> <p>31:19 Q. What were the problems associated</p> <p>31:20 with the Bard that -- the reason that you moved away</p> <p>31:21 from it?</p> <p>31:22 A. There is a database known as the</p> <p>31:23 MAUDE database and it was becoming clear that there</p> <p>31:24 were numerous reports in the literature of filter</p> <p>31:25 fragmentation and filter migration with these</p> <p>32:1 filters.</p>	03_20_18 combo final3_1.14
32:8 - 32:12	<p>D, ayala 03-21-2017 (00:00:10)</p> <p>32:8 Q. Were you called upon by a sales rep</p> <p>32:9 or somebody that's known as a detailer from Bard</p> <p>32:10 that came to your hospital to talk to you --</p> <p>32:11 A. Yes.</p> <p>32:12 Q. -- about their filters?</p>	03_20_18 combo final3_1.15
32:19 - 32:20	<p>D, ayala 03-21-2017 (00:00:01)</p> <p>32:19 Do you recall a sales rep by the name</p> <p>32:20 of Ferrara?</p>	03_20_18 combo final3_1.16
32:23 - 32:25	<p>D, ayala 03-21-2017 (00:00:07)</p> <p>32:23 A. I do.</p> <p>32:24 Q. Was he in your offices from time to</p> <p>32:25 time to talk about the Recovery and the G2?</p>	03_20_18 combo final3_1.17
33:3 - 33:3	<p>D, ayala 03-21-2017 (00:00:00)</p> <p>33:3 A. Yes.</p>	03_20_18 combo final3_1.18
33:7 - 33:13	<p>D, ayala 03-21-2017 (00:00:18)</p> <p>33:7 Q. Were you ever told by Mr. -- is it</p> <p>33:8 Ferrara?</p> <p>33:9 A. Uh-huh.</p> <p>33:10 Q. -- Mr. Ferrara that Bard had a crisis</p> <p>33:11 management plan, as early as 2004, to deal with the</p> <p>33:12 high rates of AEs, that being, adverse events,</p> <p>33:13 perforation, fracture and migration?</p>	03_20_18 combo final3_1.19
33:15 - 33:20	<p>D, ayala 03-21-2017 (00:00:18)</p> <p>33:15 THE WITNESS: No.</p>	03_20_18 combo final3_1.20

03_20_18 combo final3_1-D'AYALA 03-21-17 Booker Depo Designation Final3.1

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33:16 BY MR. MATTHEWS:

33:17 Q. Were you ever told that Bard

33:18 conducted an investigation in 2004 into the high

33:19 number or large number of adverse events of the

33:20 Recovery done by an independent investigator?

33:22 - 34:3

D, ayala 03-21-2017 (00:00:12)

03_20_18 combo final3_1.21

33:22 THE WITNESS: No.

33:23 BY MR. MATTHEWS:

33:24 Q. Were you ever sent a letter by the

33:25 company that talked to you or -- I'm sorry, that

34:1 informed you about the results of this

34:2 investigation, this independent investigation by

34:3 Bard?

34:5 - 34:10

D, ayala 03-21-2017 (00:00:13)

03_20_18 combo final3_1.22

34:5 THE WITNESS: No.

34:6 BY MR. MATTHEWS:

34:7 Q. Were you ever told, either by letter

34:8 or by Mr. Ferrara, that there was a 530 percent

34:9 higher fracture rate than other filters on the

34:10 market with the Bard Recovery?

34:12 - 34:17

D, ayala 03-21-2017 (00:00:12)

03_20_18 combo final3_1.23

34:12 THE WITNESS: No.

34:13 BY MR. MATTHEWS:

34:14 Q. Were you ever told that there was a

34:15 1,200 percent higher risk of death from the Recovery

34:16 fracture and embolization to the heart than other

34:17 filters on the market?

34:19 - 35:2

D, ayala 03-21-2017 (00:00:20)

03_20_18 combo final3_1.24

34:19 THE WITNESS: No.

34:20 BY MR. MATTHEWS:

34:21 Q. In 2004 and 2005, clearly two years

34:22 prior to implanting Ms. Booker with the G2, would

34:23 that have been important information for you to

34:24 know? Assuming that that was information that was

34:25 known to Bard, is that something that you would want

35:1 to have known?

35:2 A. Yes.

37:22 - 37:24

D, ayala 03-21-2017 (00:00:08)

03_20_18 combo final3_1.25

37:22 Q. Let me show you what's been marked as

37:23 Exhibit-3, which is the Recovery filter migration,

DAYALA 3.1.2

DAYALA 3.1.1

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
38:14 - 39:7	<p>37:24 Remedial Action Plan, dated January 4, 2005.</p> <p>D, ayala 03-21-2017 (00:00:49)</p> <p>38:14 It says, Identification of the</p> <p>38:15 problem: As part of the ongoing evaluation of RNF,</p> <p>38:16 Recovery Nitinol filter, Bard requested an</p> <p>38:17 independent study of the risks and benefits of the</p> <p>38:18 RNF, with an emphasis on its use in bariatric</p> <p>38:19 surgery and trauma patients. A consultant was</p> <p>38:20 retained for this purpose and reported the</p> <p>38:21 following: The MAUDE database maintained by the FDA</p> <p>38:22 was reviewed. The reporting rates between the RNF</p> <p>38:23 and aggregates of the other commercialized vena cava</p> <p>38:24 filters were compared.</p> <p>38:25 A, in the MAUDE dataset, the RNF</p> <p>39:1 demonstrated a consistent statistically significant</p> <p>39:2 and potentially clinically important higher rate of</p> <p>39:3 reporting of adverse events in several analyzed</p> <p>39:4 categories.</p> <p>39:5 B, given the pattern of reported</p> <p>39:6 events, a higher rate of death reports seem related</p> <p>39:7 to filter movement and filter embolization.</p>	<p>03_20_18 combo final3_1.26</p> <p>DAYALA DEPOSITION 3.5.3</p> <p>DAYALA DEPOSITION 3.6.7</p> <p>DAYALA DEPOSITION 3.6.8</p> <p>DAYALA DEPOSITION 3.6.9</p> <p>DAYALA DEPOSITION 3.6.10</p>
39:24 - 40:2	<p>D, ayala 03-21-2017 (00:00:10)</p> <p>39:24 Q. In looking at A and B, Doctor, is</p> <p>39:25 that the type of information that's important to you</p> <p>40:1 to know prior to implanting a Recovery filter?</p>	<p>03_20_18 combo final3_1.27</p> <p>DAYALA DEPOSITION 3.6.5</p>
41:16 - 42:1	<p>40:2 A. Yes.</p> <p>D, ayala 03-21-2017 (00:00:28)</p> <p>41:16 Q. Let me ask you this: As chief of</p> <p>41:17 vascular surgery at Methodist Hospital, did you have</p> <p>41:18 input on the formulary or -- in the formulary as to</p> <p>41:19 which products would be stocked or which filters</p> <p>41:20 would be used at the hospital?</p> <p>41:21 A. Yes.</p> <p>41:22 Q. So if you, the head of vascular</p> <p>41:23 surgery said, you know, I don't want this filter but</p> <p>41:24 I want these other two filters, or what have you,</p> <p>41:25 you could have had an impact on that decision?</p>	<p>03_20_18 combo final3_1.28</p> <p>clear</p>
43:6 - 43:10	<p>42:1 A. I could have, yes.</p> <p>D, ayala 03-21-2017 (00:00:16)</p> <p>43:6 Q. Whether you have a medical opinion</p>	<p>03_20_18 combo final3_1.29</p>

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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Source

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43:12 - 43:24	<p>43:7 from your practice, from your reading, from your 43:8 research, from your treatment of patients, as to 43:9 which filter failure would be the most dangerous, 43:10 producing the most serious injury to a patient.</p> <p>D, ayala 03-21-2017 (00:00:37)</p> <p>43:12 THE WITNESS: I do. 43:13 BY MR. MATTHEWS: 43:14 Q. What's your opinion? 43:15 A. Obviously, all complications are bad, 43:16 although caval thrombosis can be devastating in 43:17 terms of lower extremity edema and dysfunction. I 43:18 think that migration or fracture are more serious 43:19 events. 43:20 Q. Were you ever told, at any time prior 43:21 to today and being shown some documents about the 43:22 MAUDE database, that Bard evaluated specifically the 43:23 MAUDE database to compare their filter with others 43:24 in 2004?</p>	<p>03_20_18 combo final3_1.30</p>
44:1 - 44:8	<p>D, ayala 03-21-2017 (00:00:19)</p> <p>44:1 THE WITNESS: No. 44:2 BY MR. MATTHEWS: 44:3 Q. Is that the type of information you 44:4 would expect a manufacturer that sets out to make a 44:5 decision, or at least look at the MAUDE information 44:6 to determine filter fracture compared to other 44:7 filters on the market, is that the type of 44:8 information you want to know about?</p>	<p>03_20_18 combo final3_1.31</p>
44:10 - 44:25	<p>D, ayala 03-21-2017 (00:00:56)</p> <p>44:10 THE WITNESS: Yes. But it's a bit 44:11 more complicated in the sense that my understanding 44:12 of the MAUDE database is that it is a voluntary 44:13 database. It's not legally required for a physician 44:14 to report a problem with an implant or a product, 44:15 although you could argue that it is ethically 44:16 required. As with any database, it has problems 44:17 with regards to vetting of data, with regards to 44:18 accuracy of data. 44:19 So if a concern existed regarding a 44:20 particular product, yes, I think that should be 44:21 brought forth and studied, scientifically studied</p>	<p>03_20_18 combo final3_1.32</p>

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
	44:22 and addressed.	
	44:23 BY MR. MATTHEWS:	
	44:24 Q. At a bare minimum, the MAUDE database	
	44:25 would be a signal, a red flag --	
45:2 - 45:6	D, ayala 03-21-2017 (00:00:08)	03_20_18 combo final3_1.33
	45:2 BY MR. MATTHEWS:	
	45:3 Q. -- a red flag that should cause and	
	45:4 promote more research into whether a product is safe	
	45:5 and effective?	
	45:6 A. Agree.	
47:2 - 47:7	D, ayala 03-21-2017 (00:00:16)	03_20_18 combo final3_1.34
	47:2 Q. But let me ask you, then, this	
	47:3 question, just so we're clear.	
	47:4 Do you rely, in part, on IFUs, that	
	47:5 is, instructions for use, with the products you	
	47:6 implant in patients?	
	47:7 A. Yes.	
47:13 - 47:15	D, ayala 03-21-2017 (00:00:09)	03_20_18 combo final3_1.35
	47:13 MR. MATTHEWS: All right. I would	
	47:14 like to mark as Exhibit-4 an IFU from the G2 filter	DAYALA 4.1.3
	47:15 system that, on the last page, is dated 10/06.	
48:11 - 49:8	D, ayala 03-21-2017 (00:00:53)	03_20_18 combo final3_1.36
	48:11 Q. Doctor, I'd like to -- I don't mean	clear
	48:12 to interrupt you, but I would like to ask a couple	
	48:13 of specific questions about this.	
	48:14 A. Please do.	
	48:15 Q. On the second -- on the right-hand	DAYALA 4.1
	48:16 column, under 7, there is a -- under E, warning, G2	
	48:17 Filter implantation, it says, Filter fracture is a	DAYALA 4.1.1
	48:18 known complication of vena cava filters.	
	48:19 Do you see that?	
	48:20 A. I do.	
	48:21 Q. It says, There have been -- There	
	48:22 have been reports of embolization of vena cava	
	48:23 filter fragments resulting in retrieval of the	
	48:24 fragment using endovascular and/or surgical	
	48:25 techniques. Most cases of filter fracture, however,	
	49:1 have been reported without any adverse clinical	
	49:2 sequelae.	
	49:3 I'd like to ask you about the first	DAYALA 4.1.2

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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49:4 sentence: Filter fracture is a known complication
49:5 of vena cava filters.

49:6 Doctor, do you read that in the IFU
49:7 to mean that the rates of filter fracture are
49:8 similar with all filters?

49:10 - 49:22

D, ayala 03-21-2017 (00:00:41)

03_20_18 combo final3_1.37

49:10 THE WITNESS: I don't read anything
49:11 about rate. I read something about complications
49:12 and about the potential for fracture. So it makes
49:13 no specific statements with regards to the incidence
49:14 of this occurrence.

49:15 BY MR. MATTHEWS:

49:16 Q. If there is evidence that the company
49:17 had, in 2006 or prior to that publication being sent
49:18 to you with the filter, and there was a showing
49:19 within the company of a 500 percent greater risk
49:20 with Bard filter compared with other filters, is
49:21 that the information -- the type of information that
49:22 you would want to know about?

49:24 - 50:4

D, ayala 03-21-2017 (00:00:17)

03_20_18 combo final3_1.38

49:24 THE WITNESS: Yes.

49:25 BY MR. MATTHEWS:

50:1 Q. Would you have informed your patient,
50:2 based on your own ethics and your own consenting
50:3 habits, would you have informed your patient about
50:4 that, if it had said that in that IFU?

50:6 - 50:9

D, ayala 03-21-2017 (00:00:12)

03_20_18 combo final3_1.39

50:6 THE WITNESS: If I thought that a
50:7 particular problem -- I'm sorry, a particular filter
50:8 was a problem, was defective in some way, I unlikely
50:9 would use that product.

50:18 - 51:10

D, ayala 03-21-2017 (00:00:51)

03_20_18 combo final3_1.40

50:18 Q. Do you expect medical device
50:19 companies to do and perform adequately powered
50:20 studies looking at the safety and the efficacy of a
50:21 product prior to its sale?
50:22 A. Yes.
50:23 Q. Do you expect a medical device
50:24 manufacturer to do proper postmarket surveillance of
50:25 that product once it gets on the market and sold

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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51:1 en masse, to follow that and inform doctors about

51:2 what they see in the marketplace?

51:3 A. Yes.

51:4 Q. Were you ever told by Bard, Mr.

51:5 Ferrara or anybody at Bard, that they had observed

51:6 higher rates of complications with Recovery, that

51:7 they placed it on a temporary commercial hold? Did

51:8 you ever know that?

51:9 ***

51:10 THE WITNESS: No.

51:15 - 51:17

D, ayala 03-21-2017 (00:00:05)

03_20_18 combo final3_1.41

51:15 Q. Were you ever told why Bard withdrew

51:16 G2 from the market?

51:17 A. No.

54:15 - 54:19

D, ayala 03-21-2017 (00:00:13)

03_20_18 combo final3_1.42

54:15 Q. Have you ever received a -- what's

54:16 called a Dear Doctor letter, sometimes called a Dear

54:17 Healthcare Provider letter, from Bard concerning its

54:18 Recovery or G2 filters?

54:19 A. Not that I recall.

55:4 - 55:8

D, ayala 03-21-2017 (00:00:12)

03_20_18 combo final3_1.43

55:4 In 2012, you wrote a paper, I think

55:5 it was called Concurrent Prophylactic Placement of

55:6 IVC Filter in Bariatric Patients.

55:7 Do you recall that?

55:8 A. I do.

55:15 - 55:15

D, ayala 03-21-2017 (00:00:07)

03_20_18 combo final3_1.44

55:15 Q. I'm going to mark this as Exhibit-5.

56:3 - 56:5

D, ayala 03-21-2017 (00:00:04)

03_20_18 combo final3_1.45

56:3 Q. And this is a paper you wrote along

56:4 with these other doctors, correct?

56:5 A. Yes.

56:13 - 57:23

D, ayala 03-21-2017 (00:01:43)

03_20_18 combo final3_1.46

56:13 Q. Concurrent Prophylactic Placement

56:14 Inferior Vena Cava Filter in Gastric Bypass, what

56:15 we're talking about is during and after placement of

56:16 inferior vena cava with patients that have had lap

56:17 bands or band surgery, whether there was a benefit

56:18 with the use of a filter with those patients; is

56:19 that correct?

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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56:20 A. Yes.

56:21 Q. And you found in the conclusion, this
 56:22 was actually presented in the Eastern Vascular
 56:23 Society in DC in September of 2011, you found that
 56:24 CPIVCF was associated with specific clinical
 56:25 features, increased healthcare resource utilization
 57:1 and higher mortality in patients undergoing
 57:2 bariatric operations. Although selected patient
 57:3 characteristics influenced surgeons to perform
 57:4 CPIVCF, this study was unable to establish an
 57:5 outcome benefit for CPIVCF.

57:6 That was a mouthful.

57:7 A. Yes.

57:8 Q. But can you tell us what that means?

57:9 A. What that means is that there appears
 57:10 to be no benefit for morbidly obese patients
 57:11 undergoing these procedures to undergo concurrent
 57:12 placement of an IVC filter.

57:13 Q. So this filter in these -- in this

57:14 particular study was used prophylactically --

57:15 A. That is correct.

57:16 Q. -- to prevent PE post surgery from a
 57:17 patient, correct?

57:18 A. Correct.

57:19 Q. And you found, with your other
 57:20 authors, that there was no benefit of the filter?

57:21 A. Correct.

57:22 Q. That's an important finding.

57:23 Do you agree?

57:25 - 57:25 **D, ayala 03-21-2017 (00:00:01)**

03_20_18 combo final3_1.47

57:25 THE WITNESS: Yes.

58:8 - 58:11 **D, ayala 03-21-2017 (00:00:07)**

03_20_18 combo final3_1.48

58:8 Q. There was a study in 1998

58:9 by Dr. Decousus called the PREPIC 1 study.

58:10 Are you familiar with that study?

58:11 A. I am.

61:18 - 61:25 **D, ayala 03-21-2017 (00:00:21)**

03_20_18 combo final3_1.49

61:18 taking into account the lack of efficacy and the
 61:19 fact there were no reduction in mortality in PREPIC
 61:20 1 and PREPIC 2, coupled with the fact that the G2

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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61:21 had a fivefold increased risk for fracture compared
61:22 to other filters.

61:23 BY MR. MATTHEWS:

61:24 Q. In 2007 would you have implanted that
61:25 filter?

62:5 - 62:24

D, ayala 03-21-2017 (00:01:08)

03_20_18 combo final3_1.50

62:5 THE WITNESS: The PREPIC 1 trial is a
62:6 great study, and it's a very interesting study. But
62:7 there are problems in this study, as there are
62:8 problems with every study. And the fundamental
62:9 problem that you have with this trial is that it
62:10 randomized patients who were candidates for caval
62:11 interruption or not; in other words, all patients
62:12 were treated with blood thinners. It doesn't really
62:13 address the question of what to do with those
62:14 patients that cannot be treated with blood thinners.
62:15 And from my review of the chart on
62:16 Ms. Booker, it was clear that she could not be
62:17 treated with blood thinners. The reason for that
62:18 was she had bleeding complications. She was, if I
62:19 recall, anemic, and she was to undergo subsequent
62:20 surgical interventions.
62:21 So her anticoagulation had to be
62:22 held, hence, PREPIC doesn't really apply to a
62:23 patient like Ms. Booker. It applies to a different
62:24 set of patients.

62:25 - 63:20

D, ayala 03-21-2017 (00:01:00)

03_20_18 combo final3_1.51

62:25 With regards to the Bard filter,
63:1 would I have used a different device if I knew at
63:2 the time that the Bard filter was not ideal or as
63:3 good as some of the other implants? The answer
63:4 would have to be yes.
63:5 BY MR. MATTHEWS:
63:6 Q. You would have used --
63:7 A. I would have used a different filter
63:8 if there was a different filter that I knew of that
63:9 was better, in terms of its safety profile.
63:10 Q. In terms of the documents that you
63:11 have, I think they are Exhibit-2 and 3, the health
63:12 hazard report and then the investigation conducted

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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63:13 by Bard that showed a fivefold increased risk for
63:14 fracture and embolization of that fracture, and you
63:15 told us that would be the type of information you
63:16 would want to know in your benefit/risk analysis,
63:17 knowing that --

63:18 A. Yes.

63:19 Q. -- and seeing that today, would that
63:20 have been enough to use another filter?

63:22 - 64:2

D, ayala 03-21-2017 (00:00:17)

03_20_18 combo final3_1.52

63:22 THE WITNESS: Difficult to say with
63:23 certainty. It would depend upon what other filters
63:24 we had at the time and what their problems would
63:25 have been. But it would have been a very important
64:1 piece of information, as far as making decisions
64:2 regarding this or any other patient, yes.

64:4 - 64:7

D, ayala 03-21-2017 (00:00:04)

03_20_18 combo final3_1.53

64:4 Q. And it would have influenced your
64:5 prescribing habit?

64:6 ***

64:7 THE WITNESS: Yes.

64:9 - 64:10

D, ayala 03-21-2017 (00:00:06)

03_20_18 combo final3_1.54

64:9 Q. Let me show you a study, I'm going to
64:10 mark this as D'Ayala Exhibit Number 7. And this is

66:19 - 67:8

D, ayala 03-21-2017 (00:00:52)

03_20_18 combo final3_1.55

66:19 Q. The conclusion of this study
66:20 by Dr. Nicholson and other doctors in different
66:21 fields of medicine found the Bard Recovery and Bard
66:22 G2 filters had high prevalence of fracture and
66:23 embolization with potentially life-threatening
66:24 sequelae.

66:25 Doctor, if you had been warned prior
67:1 to June of 2007 of this information, I know this is
67:2 dated 2010, but I'm going to ask you the question
67:3 for purposes of a hypothetical, that is, had you
67:4 known this information of this conclusion, that the
67:5 G2 had a high prevalence of fracture and
67:6 embolization with life-threatening sequelae, would
67:7 that have influenced your prescribing habits and the
67:8 use of the G2 with Ms. Booker?

67:10 - 67:10

D, ayala 03-21-2017 (00:00:02)

03_20_18 combo final3_1.56

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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70:9 - 70:13	<p>67:10 THE WITNESS: Yes.</p> <p>D, ayala 03-21-2017 (00:00:19)</p> <p>70:9 Q. Well, let me ask you this question,</p> <p>70:10 then, Doctor: If you knew back in 2007 when you</p> <p>70:11 were implanting that filter that there was even a 12</p> <p>70:12 percent probability of fracture with that filter,</p> <p>70:13 would you have used a G2?</p>	03_20_18 combo final3_1.57
70:15 - 70:20	<p>D, ayala 03-21-2017 (00:00:18)</p> <p>70:15 THE WITNESS: Unlikely.</p> <p>70:16 BY MR. MATTHEWS:</p> <p>70:17 Q. If there was a 25 percent risk of</p> <p>70:18 filter fracture, can we safely say you would not</p> <p>70:19 have used that filter?</p> <p>70:20 A. Most likely.</p>	03_20_18 combo final3_1.58
70:20 - 70:25	<p>D, ayala 03-21-2017 (00:00:16)</p> <p>70:20 A. But you have to</p> <p>70:21 understand that you have to have a way of treating</p> <p>70:22 these difficult patients. So some filter has to be</p> <p>70:23 used. And it becomes a matter of deciding which</p> <p>70:24 filter is best, so to speak. And sometimes that's</p> <p>70:25 not entirely clear.</p>	03_20_18 combo final3_1.59
73:1 - 73:3	<p>D, ayala 03-21-2017 (00:00:11)</p> <p>73:1 Q. Doctor, let me show you what has been</p> <p>73:2 marked as Exhibit-11 to your deposition, which is an</p> <p>73:3 internal document from Bard.</p>	03_20_18 combo final3_1.60
73:19 - 74:1	<p>D, ayala 03-21-2017 (00:00:22)</p> <p>73:19 Q. First let me ask you, did you ever</p> <p>73:20 use in your practice the Simon Nitinol filter,</p> <p>73:21 referred here with an acronym SNF?</p> <p>73:22 A. I have.</p> <p>73:23 Q. And that is a filter, a permanent</p> <p>73:24 filter that was in existence for many years prior to</p> <p>73:25 the G2 being cleared by the FDA, correct?</p> <p>74:1 A. Correct.</p>	03_20_18 combo final3_1.61
77:14 - 77:17	<p>D, ayala 03-21-2017 (00:00:09)</p> <p>77:14 Q. Were the adverse events associated</p> <p>77:15 with the nitinol filter or the G2 ever discussed</p> <p>77:16 with you by any of the sales reps that called on</p> <p>77:17 you?</p>	03_20_18 combo final3_1.62
77:19 - 77:19	<p>D, ayala 03-21-2017 (00:00:02)</p>	03_20_18 combo final3_1.63

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81:11 - 82:10

77:19 THE WITNESS: No.

D, ayala 03-21-2017 (00:01:02)

03_20_18 combo final3_1.64

81:11 Q. If we could move to the next one,

81:12 which is MDR69.

81:13 A. Uh-huh.

81:14 Q. Any of those notes yours?

81:15 A. Yes, that's all written by me.

81:16 Q. Okay. It says, that I can read,

81:17 Preoperative diagnosis. It's the pre-op note. DVT

81:18 PE procedure planned, IVC filter. And then

81:19 pertinent medical history, physical finding.

81:20 A. Uh-huh.

81:21 Q. Can you read that?

81:22 A. It says, Patient with history of DVT

81:23 PE.

81:24 Q. And then to significant status

81:25 changes noted. And indication is what?

82:1 A. Prevention of PE.

82:2 Q. And then that's your signature?

82:3 A. It is.

82:4 Q. 6/21/07 at 7:30?

82:5 A. Uh-huh.

82:6 Q. All right. And the next entry that

82:7 may or may not be yours, Page 71.

82:8 A. No, that's -- that's mine.

82:9 Q. It is? Okay.

82:10 A. Unmistakable.

82:11 - 82:16

D, ayala 03-21-2017 (00:00:14)

03_20_18 combo final3_1.65

82:11 Q. All right. I think that says,

82:12 37-year-old with history of DVT PE.

82:13 A. I'd be happy to translate into

82:14 English --

82:15 Q. Yes, please.

82:16 A. -- if you'd like.

83:3 - 83:13

D, ayala 03-21-2017 (00:00:39)

03_20_18 combo final3_1.66

83:3 A. Sure. 6/21/07, vascular attending,

83:4 37-year-old with history of DVT PE. Uterine

83:5 fibroids, vaginal bleed with DVT, despite

83:6 anticoagulation. Awaiting surgical intervention.

83:7 Q. Now, it says that, Agree with need

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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83:8 for IVC filter.

83:9 A. Uh-huh.

83:10 Q. And I believe you told us that that

83:11 was Dr. Martin with whom you were agreeing with; is

83:12 that right?

83:13 A. Yes.

83:14 - 83:18

D, ayala 03-21-2017 (00:00:16)

03_20_18 combo final3_1.67

83:14 it says, 37-year-old awaiting GYN surgery with

83:15 chronic DVT and PE. Agree with need for IVC filter.

83:16 Will schedule for insertion of retrievable filter

83:17 today. Risk/benefits discussed with patient,

83:18 husband, who agreed to proceed.

89:11 - 89:12

D, ayala 03-21-2017 (00:00:22)

03_20_18 combo final3_1.68

89:11 Q. specifically, Page 71, which is

89:12 one of your handwritten notes.

89:18 - 90:5

D, ayala 03-21-2017 (00:00:35)

03_20_18 combo final3_1.69

89:18 Q. In the bottom red box that was made

89:19 by the plaintiff's counsel, when you read your note

89:20 it says "retrievable" -- where it says -- the

89:21 sentence that says "retrievable," what does that

89:22 sentence say?

89:23 A. Scheduled for insertion of

89:24 retrievable filter today.

89:25 Q. And in 2007 when you were implanting

90:1 the filter in Ms. Booker, the G2 filter, you

90:2 indicated in your note, in your handwritten note,

90:3 that you were implanting it as a retrievable filter;

90:4 is that right?

90:5 A. Yes.

90:12 - 90:18

D, ayala 03-21-2017 (00:00:17)

03_20_18 combo final3_1.70

90:12 Q. And so, again, your operation was the

90:13 insertion of a retrievable IVC filter; is that

90:14 right?

90:15 A. Yes.

90:16 Q. And the filter that you chose for Ms.

90:17 Booker was a Bard G2 filter; is that right?

90:18 A. That's right.

90:22 - 91:6

D, ayala 03-21-2017 (00:00:22)

03_20_18 combo final3_1.71

90:22 Q. It was

90:23 mentioned earlier that at the time you inserted the

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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90:24 Bard G2 filter in Ms. Booker, it had not been

90:25 cleared by the FDA for retrievability.

91:1 Were you aware of that?

91:2 A. Yes.

91:3 Q. But you were also aware that it was a

91:4 filter that you were able to retrieve

91:5 percutaneously; is that right?

91:6 A. Yes.

91:7 - 91:12

D, ayala 03-21-2017 (00:00:19)

03_20_18 combo final3_1.72

91:7 Q. You testified earlier that you

91:8 implanted it as a permanent filter, yet your op

91:9 notes and your handwritten notes clearly say that

91:10 you were inserting it as a retrievable filter.

91:11 So was it implanted as a retrievable

91:12 filter?

91:15 - 91:22

D, ayala 03-21-2017 (00:00:28)

03_20_18 combo final3_1.73

91:15 THE WITNESS: When I stated that

91:16 earlier, that was based on my review of the medical

91:17 record. And my bias, I can tell you today, is to

91:18 use only retrievable filters and make every effort

91:19 at retrieving these filters, if possible. Even

91:20 permanent filters are potentially retrievable with

91:21 proper techniques, more often than not

91:22 percutaneously.

92:2 - 92:8

D, ayala 03-21-2017 (00:00:20)

03_20_18 combo final3_1.74

92:2 based on what -- your review of your

92:3 records and the history you had available to you, do

92:4 you believe, and the language that you used in your

92:5 op note and in your handwritten notes,

92:6 that this filter be retrieved when she was no longer

92:7 contraindicated for anticoagulants; is that right?

92:8 A. Yes, based on what I wrote there.

92:11 - 92:18

D, ayala 03-21-2017 (00:00:24)

03_20_18 combo final3_1.75

92:11 Q. And I assume that you don't know

92:12 whether there was any discussion with Ms. Booker or

92:13 any of her healthcare providers, after you implanted

92:14 the filter, as to whether it could or should be

92:15 retrieved; is that right?

92:16 A. I can tell you that if I intended it

92:17 to be a retrievable implant, that conversation would

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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92:23 - 93:1	92:18 have taken place with Ms. Booker. D, ayala 03-21-2017 (00:00:10)	03_20_18 combo final3_1.76
93:3 - 93:3	92:23 It would have been your practice to 92:24 discuss with her the fact that the filter was 92:25 retrievable and should be retrieved when she was no 93:1 longer contraindicated for anticoagulants? D, ayala 03-21-2017 (00:00:01)	03_20_18 combo final3_1.77
93:10 - 93:13	93:3 THE WITNESS: Yes. D, ayala 03-21-2017 (00:00:13)	03_20_18 combo final3_1.78
93:18 - 94:14	93:10 In 2007 when you implanted Ms. 93:11 Booker's G2 filter, you were aware of the potential 93:12 complications associated with that filter, were you 93:13 not? D, ayala 03-21-2017 (00:00:52)	03_20_18 combo final3_1.79
94:16 - 96:7	93:18 A. The reported complications at the 93:19 time I was aware of, I'm sure. 93:20 Q. And, in fact, you previously looked 93:21 at Exhibit-4, which was the IFU -- 93:22 A. Yes. 93:23 Q. -- for the G2 filter. 93:24 And you would have had that IFU 93:25 available to you before you implanted Ms. Booker's 94:1 filter, correct? 94:2 A. Yes. 94:3 Q. And, specifically, in Section G of 94:4 the IFU, it discusses that one of the known 94:5 complications of the G2 filter is movement or 94:6 migration; is that right? 94:7 A. It does. 94:8 Q. And it also specifically addresses 94:9 that filter fracture is a known complication of vena 94:10 cava filters, does it not? 94:11 A. It does. 94:12 Q. And, in fact, fracture is a 94:13 complication of all vena cava filters, isn't it? 94:14 A. It is. As is migration. D, ayala 03-21-2017 (00:02:07)	03_20_18 combo final3_1.80
	94:16 And the G2 -- and the IFU for the G2 94:17 filter that you implanted in Ms. Booker specifically 94:18 says that, There have been reports of embolization	

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94:19 of vena cava filter fragments resulting in retrieval
 94:20 of the fragment using endovascular and/or surgical
 94:21 techniques. Most cases a filter fracture, however,
 94:22 have been reported without any adverse clinical
 94:23 sequelae.

94:24 Is that right?

94:25 A. Uh-huh.

95:1 Q. And so before treating Ms. Booker in

95:2 2007, you were aware, as you've stated, that filter

95:3 fracture was a risk associated with a G2 and all

95:4 filters; is that right?

95:5 A. Yes.

95:6 Q. And you took that into consideration

95:7 when weighing the risk/benefit for implanting a G2

95:8 filter in Ms. Booker; is that right?

95:9 A. Yes.

95:10 Q. You testified earlier that Ms.

95:11 Booker, because of what was going on in her medical

95:12 condition, was contraindicated for anticoagulants at

95:13 the time you inserted the filter, correct?

95:14 A. Yes.

95:15 Q. But she had a history of both PE and

95:16 DVT, correct?

95:17 A. Correct.

95:18 Q. And she was about to undergo surgery

95:19 for a cervical mass; is that right?

95:20 A. Right.

95:21 Q. And so she had to be removed from the

95:22 anticoagulant medication?

95:23 A. Right.

95:24 Q. But it was your -- was it your

95:25 understanding that post surgery that medication

96:1 would be resumed, or did you have an understanding

96:2 of that?

96:3 A. I'm not entirely sure that that is

96:4 clear to me from the record. I can tell you that it

96:5 would be my practice to discuss resumption of

96:6 anticoagulation with all of the physicians involved

96:7 in her care.

96:17 - 97:17

D, ayala 03-21-2017 (00:01:17)

03_20_18 combo final3_1.81

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96:17 Q. -- in your handwritten note it says,
 96:18 Risk/benefits discussed with patient.
 96:19 Is that right? I hope that's what it
 96:20 says.
 96:21 A. Yes.
 96:22 Q. Schedule for insertion --
 96:23 A. Yes.
 96:24 Q. -- of retrievable filter today?
 96:25 A. Yes. Risks/benefits discussed with
 97:1 patient, husband, who agreed to proceed.
 97:2 Q. And what was your practice at the
 97:3 time, do you recall -- at the time in 2007, what
 97:4 risk/benefits would you have discussed with Ms.
 97:5 Booker relating to the insertion of the retrievable
 97:6 filter?
 97:7 A. Right. What I would discuss with any
 97:8 young patient regarding any implant is concerns
 97:9 regarding durability, procedural complications. I
 97:10 would discuss the potential for bleeding, infection;
 97:11 a dye reaction, very unlikely, some degree of renal
 97:12 insufficiency as the complication of the use of dye.
 97:13 And as far as long-term
 97:14 complications, as I stated, durability and the
 97:15 potential for caval thrombosis, migration,
 97:16 fragmentation. Hence, the importance for follow-up
 97:17 and attempt at retrieval in the future.

99:25 - 100:14

D, ayala 03-21-2017 (00:00:47)

03_20_18 combo final3_1.82

99:25 Q. Based on your review of the
 100:1 medical records, did you see, treat Ms. Booker after
 100:2 the implantation of the filter?
 100:3 A. No. I saw her the day afterwards,
 100:4 based on these records, which, as we discussed
 100:5 previously, is customary.
 100:6 I have no personal office records of
 100:7 Ms. Booker ever seeing me after hospital discharge.
 100:8 Q. Would it have -- was it your practice
 100:9 in 2007 to recommend that a patient come back and
 100:10 see you at least once after discharge?
 100:11 A. Yes.
 100:12 Q. But as far as your records indicate,

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

Page/Line	Source	ID
	100:13 Ms. Booker never did that?	
	100:14 A. Yes.	
100:15 - 101:17	D, ayala 03-21-2017 (00:01:11)	03_20_18 combo final3_1.83
	100:15 Q. Doctor, at the beginning of the	
	100:16 deposition you were shown a handful of internal	
	100:17 documents from Bard, specifically you were shown two	
	100:18 Bard internal documents and an e-mail.	
	100:19 Do you recall those?	
	100:20 A. I do.	
	100:21 Q. Have you ever been shown internal	
	100:22 documents from any other device manufacturer?	
	100:23 A. No.	
	100:24 Q. Have you ever requested internal	
	100:25 documents from a device manufacturer in performing a	
	101:1 risk/benefit analysis --	
	101:2 A. No.	
	101:3 Q. -- of a product?	
	101:4 Do you know -- was today the first	
	101:5 time you had ever seen Exhibits-2 and 3?	
	101:6 A. Yes.	
	101:7 Q. And you did not have the opportunity	
	101:8 to read those exhibits in their entirety, did you?	
	101:9 A. No.	
	101:10 Q. But both of the exhibits on their	
	101:11 face indicate that they are about the Recovery	
	101:12 filter, do they not?	
	101:13 A. Indeed.	
	101:14 Q. And, in fact, the filter that you	
	101:15 implanted in Ms. Booker was not a Bard Recovery	
	101:16 filter, was it?	
	101:17 A. That is correct.	
101:24 - 102:9	D, ayala 03-21-2017 (00:00:18)	03_20_18 combo final3_1.84
	101:24 Q. it looks like Bard was doing an	
	101:25 internal analyzation of its Recovery filter,	
	102:1 correct?	
	102:2 A. It does.	
	102:3 Q. And you don't know what Bard did in	
	102:4 response to this internal evaluation; is that right?	
	102:5 A. I do not.	
	102:6 Q. And you don't know what changes Bard	
Plaintiffs Designations	Defense Designations	Plaintiffs and defense Designations

Page/Line	Source	ID
104:2 - 104:6	<p>102:7 made between the Recovery filter and the G2 filter, 102:8 do you? 102:9 A. No.</p> <p>D, ayala 03-21-2017 (00:00:12)</p> <p>104:2 Q. Have you ever been provided with 104:3 comparative rate data from manufacturers regarding 104:4 any product that you use, any medical device that 104:5 you use? 104:6 A. Not to my knowledge.</p>	03_20_18 combo final3_1.85
105:12 - 106:1	<p>D, ayala 03-21-2017 (00:00:26)</p> <p>105:12 Q. When it comes to making decisions for 105:13 your patients and weighing the risk and benefits of 105:14 medical devices that you use with your patients, you 105:15 rely on a number of sources, don't you? 105:16 A. I do. 105:17 Q. You rely on the FDA? 105:18 A. Yes. 105:19 Q. You rely on your partners and 105:20 colleagues? 105:21 A. Yes. 105:22 Q. You rely on available medical 105:23 literature regarding the device or the product? 105:24 A. Yes. 105:25 Q. You rely on your own experiences? 106:1 A. I do.</p>	03_20_18 combo final3_1.86
106:11 - 106:15	<p>D, ayala 03-21-2017 (00:00:13)</p> <p>106:11 Q. And you would not want to receive 106:12 unreliable or preliminary or internal investigations 106:13 without knowing the outcome or the results; is that 106:14 right? 106:15 A. That's right.</p>	03_20_18 combo final3_1.87
108:18 - 109:12	<p>D, ayala 03-21-2017 (00:00:54)</p> <p>108:18 Q. Have you ever seen any peer-reviewed 108:19 literature saying that the G2 filter has 108:20 complication rates that are significantly higher 108:21 than other filters? 108:22 A. No. 108:23 Q. So sitting here today, you're not 108:24 aware of any medical literature that shows that the 108:25 complication rates for the G2 filter are higher than</p>	03_20_18 combo final3_1.88

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109:1 any other filters that were available; is that
 109:2 right?
 109:3 A. I would rephrase that by saying I
 109:4 have not seen any literature that directly compares
 109:5 the G2 filter to any other filter and states that
 109:6 that filter is more dangerous or less efficacious.
 109:7 Q. Thank you.
 109:8 Have you ever seen any FDA
 109:9 denouncement saying the G2 filter has complication
 109:10 rates that are significantly higher than other
 109:11 filters?
 109:12 A. I have not.

111:18 - 112:7

D, ayala 03-21-2017 (00:00:35)

03_20_18 combo final3_1.89

111:18 Q. You would expect them to be looking
 111:19 at reports of adverse events from the -- from
 111:20 patients and analyzing their filters and
 111:21 continuously looking to improve the product; is that
 111:22 right?
 111:23 A. Yes.
 111:24 Q. And you would agree with me that
 111:25 that's part of the risk/benefit analysis that a
 112:1 manufacturer should do before bringing a product to
 112:2 market, correct?
 112:3 A. Yes.
 112:4 Q. You would also agree with me that
 112:5 within -- with any medical device there are risks?
 112:6 A. Absolutely.
 112:7 Q. And with any medical device there are

112:10 - 112:12

D, ayala 03-21-2017 (00:00:04)

03_20_18 combo final3_1.90

112:10 again -- there are risks that may come to light
 112:11 after the product is on the market?
 112:12 A. Yes.

114:8 - 114:15

D, ayala 03-21-2017 (00:00:13)

03_20_18 combo final3_1.91

114:8 Do you recall any specific
 114:9 discussions you had with the sales reps from Bard
 114:10 regarding the G2 filter?
 114:11 A. No.
 114:12 Q. Do you recall ever raising any
 114:13 questions or concerns with the sales reps regarding
 114:14 the G2 filter?

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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115:7 - 115:14	<p>114:15 A. No.</p> <p>D, ayala 03-21-2017 (00:00:16)</p> <p>115:7 Do you know if medical device</p> <p>115:8 manufacturers are even permitted to provide doctors</p> <p>115:9 with alleged complication rates, comparative</p> <p>115:10 complication rates under the FDA guidelines?</p> <p>115:11 A. I do not.</p> <p>115:12 Q. And that's not something anyone has</p> <p>115:13 ever provided to you, though, is it?</p> <p>115:14 A. No, it is not.</p>	03_20_18 combo final3_1.92
121:6 - 121:15	<p>D, ayala 03-21-2017 (00:00:22)</p> <p>121:6 Q. Doctor, you were asked a number of</p> <p>121:7 times today, if something is true, would that have</p> <p>121:8 impacted your decision of whether to use a certain</p> <p>121:9 filter or not.</p> <p>121:10 Do you recall those questions?</p> <p>121:11 A. Yes, I do.</p> <p>121:12 Q. What you have not been provided today</p> <p>121:13 is with any peer-reviewed or reliable information</p> <p>121:14 showing that those "ifs" are, in fact, true; is that</p> <p>121:15 right?</p>	03_20_18 combo final3_1.93
121:19 - 121:19	<p>D, ayala 03-21-2017 (00:00:01)</p> <p>121:19 THE WITNESS: I agree.</p>	03_20_18 combo final3_1.94
121:21 - 122:1	<p>D, ayala 03-21-2017 (00:00:18)</p> <p>121:21 Q. And for you to make an evaluation and</p> <p>121:22 to make a decision relating to whether you would</p> <p>121:23 have done something or not, it would be important</p> <p>121:24 for you to have reliable and complete information;</p> <p>121:25 is that right?</p> <p>122:1 A. Yes.</p>	03_20_18 combo final3_1.95
126:1 - 126:2	<p>D, ayala 03-21-2017 (00:00:04)</p> <p>126:1 Q. Just a few more questions, Doctor, in</p> <p>126:2 response to some questions that you were just asked.</p>	03_20_18 combo final3_1.96
126:10 - 126:21	<p>D, ayala 03-21-2017 (00:00:48)</p> <p>126:10 Q. Had you known at the time of implant</p> <p>126:11 that there was up to a 25 percent risk of a</p> <p>126:12 fractured filter in the G2, would you have taken</p> <p>126:13 steps to ensure that that filter was retrieved from</p> <p>126:14 Ms. Booker after implant?</p> <p>126:15 A. Yes.</p>	03_20_18 combo final3_1.97

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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126:23 - 127:11	<p>126:16 Q. If you would have known there was up 126:17 to a 25 percent risk of filter fracture in that G2, 126:18 as we've seen in the articles in front of you, you 126:19 would have taken greater steps than what were taken 126:20 to make sure that filter was removed after implant 126:21 with that patient on that -- in that year, correct?</p> <p>D, ayala 03-21-2017 (00:00:45)</p> <p>126:23 THE WITNESS: Knowing what I today, I 126:24 think it's safe to answer that question as yes. 126:25 Given the information we had at hand back then, I'm 127:1 not so sure anything would have changed. But, yes, 127:2 we make an effort to follow our patients back then 127:3 as now. 127:4 BY MR. MATTHEWS: 127:5 Q. Let me ask you about that, in terms 127:6 of the fracture rate. 127:7 Has Bard ever suggested a protocol 127:8 for your hospital, knowing what we know today, to 127:9 follow those patients that had Recovery and G2 127:10 filters to make sure that they are retrieved once 127:11 the risk of PE has subsided?</p>	03_20_18 combo final3_1.98
127:13 - 127:13	<p>D, ayala 03-21-2017 (00:00:01)</p> <p>127:13 THE WITNESS: No.</p>	03_20_18 combo final3_1.99
127:19 - 128:2	<p>D, ayala 03-21-2017 (00:00:17)</p> <p>127:19 Q. Doctor, the decision of whether or 127:20 how to treat a follow-up patient, you would agree 127:21 with me that's a medical decision, wouldn't you? 127:22 A. Yes. 127:23 Q. And it needs to be made by a medical 127:24 doctor with medical training? 127:25 A. Yes. 128:1 Q. And not by a device manufacturer? 128:2 A. Yes.</p>	03_20_18 combo final3_1.100
10:12 - 10:17	<p>D, ayala 03-21-2017 (00:00:09)</p> <p>10:12 Doctor, could you state your name, 10:13 please? 10:14 A. Marcus D'Ayala. 10:15 Q. And what do you do, sir? 10:16 A. I'm a vascular surgeon in clinical 10:17 practice in Brooklyn, New York.</p>	03_20_18 combo final3_1.101

03_20_18 combo final3_1-D'Ayala 03-21-17 Booker Depo Designation Final3.1

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Plaintiffs Designations = 00:23:55

Defense Designations = 00:16:37

Plaintiffs and defense Designations = 00:00:50

Total Time = 00:41:22**Documents Shown**

DAYALA 3

DAYALA 4

DAYALA DEPOSITION 3

EXHIBIT F

Designation Run Report

Kang 06-15-17 Booker Depo Designations FINAL5

Kang, Brandon 06-15-2017

Plaintiffs Designations 00:17:47

Defense Designations 00:14:40

Plaintiffs And Defense Designations 00:01:18

Total Time 00:33:45



03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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6:13 - 6:14	Kang, Brandon 06-15-2017 (00:00:04) 6:13 Q. All right. Good morning, Dr. Kang. 6:14 A. Good morning.	03_20_18 combo FINAL5.1
9:5 - 9:10	Kang, Brandon 06-15-2017 (00:00:07) 9:5 Q. Are you licensed to practice medicine in any 9:6 state? 9:7 A. Yes, I am. 9:8 Q. Of course. And would that be the state of 9:9 Georgia? 9:10 A. In the state of Georgia.	03_20_18 combo FINAL5.2
10:13 - 10:21	Kang, Brandon 06-15-2017 (00:00:34) 10:13 Q. Now, could you tell us whether or not you've 10:14 had experience in implanting and removing IVC filters? 10:15 A. I have extensive experience in placing and 10:16 removing IVC filters. I first started placing these 10:17 even when I was in residency during training, and 10:18 then a lot of experience during my fellowship and 10:19 postfellowship at Emory implanting pretty much all 10:20 the various types of filters that are out there and 10:21 removing the ones that were retrievable as well.	03_20_18 combo FINAL5.3
11:11 - 11:15	Kang, Brandon 06-15-2017 (00:00:15) 11:11 Q. Now, in your capacity, and in your 11:12 profession as an interventional radiologist at 11:13 Gwinnett Medical Center, did you have occasion to 11:14 treat Ms. Sherr-Una Booker? 11:15 A. Yes, I did.	03_20_18 combo FINAL5.4
11:19 - 11:23	Kang, Brandon 06-15-2017 (00:00:34) 11:19 Q. I'm going to hand you what I'm marking as 11:20 Exhibit 3 and represent to you that this is the 11:21 emergency department physician note dated June 26, 11:22 2014. 11:23 A. Okay.	03_20_18 combo FINAL5.5
11:24 - 12:18	Kang, Brandon 06-15-2017 (00:01:02) 11:24 Q. could you just explain the circumstances 11:25 under which you came to treat Ms. Booker? 12:1 A. So Ms. Booker was seen in the emergency 12:2 department, according to this record, on June 26, 12:3 2004. Came in with abdominal pain. During the 12:4 workup process, looks like they did a CT scan, which 12:5 showed some -- an IVC filter in place and a fragment	03_20_18 combo FINAL5.6

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12:6 or a couple fragments, one that was dislodged into
 12:7 the heart and one that was dislodged in the IVC
 12:8 itself.
 12:9 After the ER doc spoke to the on-call
 12:10 radiologist or the radiologist who read the film, he
 12:11 thought that it would be prudent for her to come see
 12:12 me in my office to discuss the possible retrieval of
 12:13 the IVC filter and the fragments.
 12:14 So she basically had an appointment. They
 12:15 didn't call me directly from the emergency
 12:16 department, so they must have given her my
 12:17 information to follow up with me and she came to see
 12:18 me in my clinic.

13:7 - 13:9

Kang, Brandon 06-15-2017 (00:00:05)

03_20_18 combo FINAL5.7

13:7 Q. And this is your record of
 13:8 Ms. Booker's visit to you on July 3?
 13:9 A. Correct.

2350_MEDICAL.1.2

2350_MEDICAL.1.1

15:13 - 15:16

Kang, Brandon 06-15-2017 (00:00:13)

03_20_18 combo FINAL5.8

15:13 Q. Based upon your conversation and observation
 15:14 of Ms. Booker on July 3, would you state what her
 15:15 mental attitude was about the retention of the
 15:16 fractured components of the filter?

clear

15:21 - 16:25

Kang, Brandon 06-15-2017 (00:01:27)

03_20_18 combo FINAL5.9

15:21 A. Okay. My recollection is, you know, she was
 15:22 nervous with what had happened, especially after I
 15:23 showed her the pieces that had broken off, about what
 15:24 would potentially happen to her if it was left in
 15:25 place.

16:1 Q. Okay. And could you describe to the jury
 16:2 where these fractured pieces of the filter were in her
 16:3 body --

16:4 A. Right.

16:5 Q. -- on July 3?

16:6 A. I didn't have the luxury of seeing when the
 16:7 initial filter was placed and/or how it was placed
 16:8 and how it was positioned, but from my review of the
 16:9 images that we had, because I also got an x-ray of
 16:10 the abdomen and the heart as well, the chest as well
 16:11 during the consultation, and, basically, the filter
 16:12 was tilted to one side, looked like at least three of

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16:13 the legs had possibly broken off, one was in the
 16:14 region of the right ventricle, and two additional
 16:15 fragments, one is laying in the cava and then the
 16:16 other one was actually penetrating through the cava,
 16:17 inferior vena cava, into the aorta as well.

16:18 Q. So when you say right ventricle, what part of
 16:19 the body is that?

16:20 A. So that's the part of the right side of the
 16:21 heart. The heart has four chambers. All the blood
 16:22 comes into the right atrium, then it goes through the
 16:23 tricuspid valve into the right ventricle, and then it
 16:24 goes into the lungs, then comes back from the lungs
 16:25 into the left atrium and the left ventricle.

17:19 - 17:20

Kang, Brandon 06-15-2017 (00:00:03)

03_20_18 combo FINAL5.10

17:19 Q. please describe where those two other
 17:20 filters were located --

17:22 - 18:2

Kang, Brandon 06-15-2017 (00:00:12)

03_20_18 combo FINAL5.11

17:22 Q. -- those two fragments were located.
 17:23 A. One of the fragments was penetrating the
 17:24 inferior vena cava and hitting the aorta itself, and
 17:25 then the other one had broken off and was just
 18:1 sitting in the -- probably the wall of the inferior
 18:2 vena cava.

19:6 - 19:10

Kang, Brandon 06-15-2017 (00:00:09)

03_20_18 combo FINAL5.12

19:6 Q. With regard to the fragment that was hitting
 19:7 the aorta, could you tell if it had pierced the aorta
 19:8 or not?

19:9 A. On imaging, yes, it looked like it had
 19:10 penetrated into the aorta.

20:10 - 20:13

Kang, Brandon 06-15-2017 (00:00:08)

03_20_18 combo FINAL5.13

20:10 Q. And did you form an opinion
 20:11 specifically with regard to the fragment in the right
 20:12 ventricle as to whether it was in the best interest of
 20:13 the patient to remove?

20:15 - 20:23

Kang, Brandon 06-15-2017 (00:00:33)

03_20_18 combo FINAL5.14

20:15 A. So the fragment in the right ventricle
 20:16 proposed a problem for the patient because the heart
 20:17 is a continuously pumping moving part in the body,
 20:18 and as such, the filter fragment could have further
 20:19 migrated, could have penetrated through the wall of

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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20:20 the right ventricle itself, caused pericardial
 20:21 hemorrhage and pericardial tamponade, and potentially
 20:22 death as a result of the fragment sitting there in
 20:23 the moving part.

21:13 - 21:16

Kang, Brandon 06-15-2017 (00:00:07)

03_20_18 combo FINAL5.17

21:13 Q. Would you state whether or not you had formed
 21:14 an opinion that it was prudent and in the best
 21:15 interest of the patient to remove the fragment from
 21:16 the heart?

21:18 - 21:20

Kang, Brandon 06-15-2017 (00:00:11)

03_20_18 combo FINAL5.18

21:18 A. Yes, I thought it would be potentially a
 21:19 procedure that we could do that would prevent her
 21:20 from having a more invasive open heart surgery.

22:16 - 22:23

Kang, Brandon 06-15-2017 (00:00:10)

03_20_18 combo FINAL5.19

22:16 Q. Did you consult with a
 22:17 cardiothoracic surgeon --

22:18 A. Yes.

22:19 Q. -- on the issue of the fragment in
 22:20 Ms. Booker's heart?

22:21 A. Yes, absolutely, and I sent Ms. Booker to the
 22:22 cardiothoracic surgeon and I spoke with him directly
 22:23 as well.

24:6 - 24:10

Kang, Brandon 06-15-2017 (00:00:19)

03_20_18 combo FINAL5.20

24:6 Q. So having obtained a
 24:7 cardiothoracic surgery consult, and having reviewed
 24:8 the CT scan of June of 2014, could you tell the jury
 24:9 then what your plan was in your approach with regard
 24:10 to Ms. Booker?

24:12 - 24:18

Kang, Brandon 06-15-2017 (00:00:21)

03_20_18 combo FINAL5.21

24:12 A. So the first thing I wanted to do was remove
 24:13 the remaining IVC filter in its entirety, and then
 24:14 the second plan was to go after the fragments that
 24:15 were left in the inferior vena cava and the one
 24:16 penetrating the aorta, and then lastly, I wanted to
 24:17 go in and potentially remove the fragment from her
 24:18 heart.

27:11 - 27:15

Kang, Brandon 06-15-2017 (00:00:11)

03_20_18 combo FINAL5.22

27:11 Q. If you could just
 27:12 look at Exhibit 7 and, in fact, identify what it is
 27:13 for us?

2368_MIR.1.1

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

Page/Line	Source	ID
	27:14 A. So this is the actual procedure report that 27:15 was performed on 7/23.	2368_MR.1.2
27:25 - 28:9	Kang, Brandon 06-15-2017 (00:00:35) 27:25 Q. All right. And is Ms. Booker, is she awake 28:1 during this procedure? Or describe the level of 28:2 sedation, might be a better way to ask you. 28:3 A. So she is not under general anesthesia means 28:4 that she is given moderate sedation with Versed and 28:5 fentanyl, so she will be sleepy throughout the 28:6 process, but a lot of times we can wake the patient 28:7 up, talk to them if needed, or sometimes they do fall 28:8 asleep, a very light sleep where they don't need a 28:9 breathing tube or anything like that.	03_20_18 combo FINAL5.23 clear
28:21 - 28:22	Kang, Brandon 06-15-2017 (00:00:03) 28:21 Q. And what was the filter?	03_20_18 combo FINAL5.24
30:25 - 31:10	28:22 A. It was a Bard G2 filter. Kang, Brandon 06-15-2017 (00:00:34) 30:25 Q. Her jugular vein. And what type of 31:1 instrument are you putting into her jugular vein? 31:2 A. So the first thing that goes in is a needle, 31:3 and then a wire. We take the needle out, we make the 31:4 hole a little bit bigger, and then we put a sheath in 31:5 which guides our tools and instruments in to 31:6 potentially remove the filter, and that's where we 31:7 put -- that's called the sheath, and we put a sheath 31:8 in there and then we deploy the Recovery set to see 31:9 if we can -- Recovery Cone System to see if we could 31:10 take the filter out.	03_20_18 combo FINAL5.26
32:3 - 32:14	Kang, Brandon 06-15-2017 (00:00:31) 32:3 Q. that Recovery System that Bard 32:4 recommended you use or provided to you to use, did 32:5 that work in this case? 32:6 A. In this case it did not work. 32:7 Q. And why did it not work? 32:8 A. My experience has been with -- although 32:9 sometimes we can remove it when the filters are 32:10 slightly tilted, this filter was tilted even more 32:11 where I felt the apex of the filter was touching the 32:12 wall of the inferior vena cava, making the discovery 32:13 a little more difficult, so we had to use advanced	03_20_18 combo FINAL5.107

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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35:4 - 35:7	<p>32:14 techniques.</p> <p>Kang, Brandon 06-15-2017 (00:00:12)</p> <p>35:4 Q. All right. And during this procedure that</p> <p>35:5 we've been talking about on July 23rd, you were able</p> <p>35:6 to successfully remove the filter?</p> <p>35:7 A. The filter, yes.</p>	03_20_18 combo FINAL5.30
35:16 - 35:23	<p>Kang, Brandon 06-15-2017 (00:00:21)</p> <p>35:16 Q. After you</p> <p>35:17 removed the filter, then what three fragment filters</p> <p>35:18 were remaining and where were they?</p> <p>35:19 A. So after the filter was removed, there was</p> <p>35:20 one filter fragment remaining in the heart;</p> <p>35:21 one filter -- well, two filter fragments remaining in</p> <p>35:22 the inferior vena cava, one of which was penetrating</p> <p>35:23 the aorta.</p>	03_20_18 combo FINAL5.33
36:17 - 36:23	<p>Kang, Brandon 06-15-2017 (00:00:14)</p> <p>36:17 Q. And you were able, through this maneuvering,</p> <p>36:18 to lasso the fragment that had pierced the wall of the</p> <p>36:19 vena cava and into the aorta?</p> <p>36:20 A. Yes, I was.</p> <p>36:21 Q. And grab it and remove it from Ms. Booker's</p> <p>36:22 body?</p> <p>36:23 A. Yes.</p>	03_20_18 combo FINAL5.108
37:13 - 37:24	<p>Kang, Brandon 06-15-2017 (00:00:33)</p> <p>37:13 Q. What was your next step during this</p> <p>37:14 procedure?</p> <p>37:15 A. And then an attempt was made -- there is that</p> <p>37:16 second fragment in the inferior vena cava, and so I</p> <p>37:17 went to try to grab that fragment and I was</p> <p>37:18 unsuccessful in removing that fragment.</p> <p>37:19 Q. And why was that?</p> <p>37:20 A. Potentially, the way it was laying in the</p> <p>37:21 inferior vena cava, basically along the wall, there</p> <p>37:22 was difficult -- it was difficult -- there was</p> <p>37:23 nothing potentially sticking out for me to grab with</p> <p>37:24 the snare.</p>	03_20_18 combo FINAL5.35
38:16 - 39:2	<p>Kang, Brandon 06-15-2017 (00:00:39)</p> <p>38:16 Q. All right. And describe for me the route of</p> <p>38:17 going in in an attempt to get the filter. What</p> <p>38:18 structures, what chambers, what anatomical parts did</p>	03_20_18 combo FINAL5.109

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38:19 you advance through in order to gain access or
38:20 attempted access to the --

38:21 A. Sure. So from the inferior vena cava we go
38:22 to the right atrium, and from there we go through the
38:23 tricuspid valve into the right ventricle, where the
38:24 filter fragment was.

38:25 Q. Okay. Is the right ventricle below the right
39:1 atrium?

39:2 A. Yes.

39:19 - 39:21

Kang, Brandon 06-15-2017 (00:00:06)

03_20_18 combo FINAL5.110

39:19 Q. Did its location make it more
39:20 difficult to retrieve using the percutaneous approach,
39:21 in your opinion?

39:23 - 39:24

Kang, Brandon 06-15-2017 (00:00:05)

03_20_18 combo FINAL5.36

39:23 A. Yes, the location made it a little bit more
39:24 difficult.

40:4 - 40:11

Kang, Brandon 06-15-2017 (00:00:20)

03_20_18 combo FINAL5.111

40:4 Q. Now, just to be sort of clear in our mind, in
40:5 order to access this fragment in the right ventricle,
40:6 you go through the right atrium, correct?

40:7 A. Yes.

40:8 Q. And you have to advance an instrument through
40:9 the valve that separates the right atrium from the
40:10 right ventricle?

40:11 A. That is correct.

40:13 - 40:24

Kang, Brandon 06-15-2017 (00:00:41)

03_20_18 combo FINAL5.37

40:13 Q. What's the name of that valve?

40:14 A. The tricuspid valve.

40:15 Q. Right. So what was your next step in the
40:16 procedure?

40:17 A. So as one last effort to remove the filter
40:18 fragment, we thought that possibly coming from a
40:19 different angle would -- could possibly work, so we
40:20 reaccessed the jugular vein, and then from there you
40:21 go into the superior vena cava, into the right
40:22 atrium, and into the right ventricle, and we tried,
40:23 basically, the same technique from a different angle
40:24 and that was unsuccessful as well.

42:17 - 42:18

Kang, Brandon 06-15-2017 (00:00:04)

03_20_18 combo FINAL5.41

42:17 Q. Would you state whether or not

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42:21 - 43:3

42:18 that was a prudent decision to make at the time?

Kang, Brandon 06-15-2017 (00:00:21)

03_20_18 combo FINAL5.42

42:21 A. I felt like at that point in time it was a
 42:22 good decision to stop and stand instead of trying to
 42:23 continue on.

42:24 Q. Do you have an opinion as to whether at all
 42:25 times during your performance of this procedure that
 43:1 you conformed with the standard of care exercised by
 43:2 physicians generally under like surrounding
 43:3 circumstances and similar conditions?

43:6 - 43:19

Kang, Brandon 06-15-2017 (00:00:48)

03_20_18 combo FINAL5.43

43:6 A. Yes, I believe this is well within the
 43:7 standard of care.

43:8 Q. Upon either during the procedure or upon
 43:9 conclusion of your procedure that you just described
 43:10 for us, did you have an occasion to consult with
 43:11 cardiology regarding Ms. Booker?
 43:12 A. So before the procedure even started, I
 43:13 called a cardiothoracic surgeon to let him know that
 43:14 we were starting the case, so they were on standby
 43:15 just because of the potential risks that were there.
 43:16 And then after the procedure, when she had
 43:17 some chest discomfort and with the irregular
 43:18 heartbeat that she had developed, we did call
 43:19 cardiology for a consultation to come and assess her.

43:21 - 44:2

Kang, Brandon 06-15-2017 (00:00:19)

03_20_18 combo FINAL5.44

43:21 At the conclusion of your
 43:22 procedure, what fragments, if any, were still left in
 43:23 Ms. Booker's body from this filter?

43:24 A. So after the conclusion of my procedure,
 43:25 there was one fragment that remained in the right
 44:1 ventricle and one fragment that remained in the
 44:2 inferior vena cava.

44:8 - 44:20

Kang, Brandon 06-15-2017 (00:00:48)

03_20_18 combo FINAL5.45

44:8 Q. Approximately how long did this procedure
 44:9 take?

44:10 A. Well, she was under sedation for 94 minutes,
 44:11 so hour-and-a-half total.

44:12 Q. Okay. Was it explained to her after the
 44:13 procedure, while she was recovering, that the

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44:14 percutaneous procedure of yours was not successful in
44:15 obtaining the fragment from her heart and one in the
44:16 vena cava?

44:17 A. So, yes, after the procedure we had told her
44:18 that we were able to remove the filter and one filter
44:19 fragment, and then we had told her that she had two
44:20 additional fragments that remained in her -- in her.

45:11 - 45:13

Kang, Brandon 06-15-2017 (00:00:09)

03_20_18 combo FINAL5.46

45:11 Q. Okay. And would you state whether or not
45:12 Ms. Booker was anxious or upset about the fact that
45:13 these fragments could not be removed from her body?

45:15 - 45:15

Kang, Brandon 06-15-2017 (00:00:02)

03_20_18 combo FINAL5.47

45:15 Q. Based on your observation with her?

45:17 - 45:24

Kang, Brandon 06-15-2017 (00:00:25)

03_20_18 combo FINAL5.48

45:17 A. So my recollection is that she was -- she had
45:18 some mixed feelings: One, that she was happy that we
45:19 were able to at least get the filter fragment -- the
45:20 filter itself and one fragment out, but at the same
45:21 time she was very anxious about what would transpire
45:22 with the two filter fragments that were unable to be
45:23 removed, with the potential of needing open heart
45:24 surgery to have those removed.

46:25 - 47:15

Kang, Brandon 06-15-2017 (00:00:51)

03_20_18 combo FINAL5.49

46:25 Q. And based upon the testing that
47:1 was done post procedure, did you all reach any
47:2 conclusions as to whether or not there had been any
47:3 damage to Ms. Booker's tricuspid valve?

47:4 A. Yes. With the results of the echocardiogram,
47:5 it looks like she had mod range regurgitation to
47:6 suggest that there was some injury to the tricuspid
47:7 valve.

47:8 Q. Would you state whether or not this was a
47:9 complication of the percutaneous procedure?

47:10 A. In essence, I mean, it was a complication of
47:11 the attempted filter retrieval from the right
47:12 ventricle.

47:13 Q. And would you state whether or not this is
47:14 the type of complication that occurs even in the best
47:15 and skillful of physician hands?

47:18 - 47:18

Kang, Brandon 06-15-2017 (00:00:01)

03_20_18 combo FINAL5.50

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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54:16 - 54:19	<p>47:18 A. Yes.</p> <p>Kang, Brandon 06-15-2017 (00:00:10)</p> <p>54:16 Q. Were you ever told by Bard when you were</p> <p>54:17 using the Bard filters that there were no randomized</p> <p>54:18 control trials showing the decrease in mortality with</p> <p>54:19 use of Bard filter?</p>	03_20_18 combo FINAL5.53
54:21 - 54:21	<p>Kang, Brandon 06-15-2017 (00:00:01)</p> <p>54:21 A. No.</p>	03_20_18 combo FINAL5.54
55:9 - 55:10	<p>Kang, Brandon 06-15-2017 (00:00:06)</p> <p>55:9 Q. Were you ever warned by Bard that there was a</p> <p>55:10 fracture rate of over 10 percent with the G2 filter?</p>	03_20_18 combo FINAL5.55
55:12 - 55:15	<p>Kang, Brandon 06-15-2017 (00:00:09)</p> <p>55:12 A. No.</p> <p>55:13 Q. If you had been so warned by Bard, would you</p> <p>55:14 have used it in your patients?</p> <p>55:15 A. No.</p>	03_20_18 combo FINAL5.56
55:16 - 55:17	<p>Kang, Brandon 06-15-2017 (00:00:08)</p> <p>55:16 Q. If fracture was prevalent with the G2 filter,</p> <p>55:17 should doctors and patients be told this?</p>	03_20_18 combo FINAL5.57
55:19 - 56:1	<p>Kang, Brandon 06-15-2017 (00:00:24)</p> <p>55:19 Q. Would you expect this to be warned about by</p> <p>55:20 Bard?</p> <p>55:21 A. Yes, I would expect that.</p> <p>55:22 Q. Did Bard ever warn you of that?</p> <p>55:23 A. No.</p> <p>55:24 Q. Did Bard ever warn you about the rate of</p> <p>55:25 caudal migration of the Bard filter?</p> <p>56:1 A. No.</p>	03_20_18 combo FINAL5.58
59:1 - 59:2	<p>Kang, Brandon 06-15-2017 (00:00:06)</p> <p>59:1 Q. Based upon your contact with Ms. Booker,</p> <p>59:2 would you describe her as a compliant patient?</p>	03_20_18 combo FINAL5.59
59:4 - 59:9	<p>Kang, Brandon 06-15-2017 (00:00:22)</p> <p>59:4 A. Yes.</p> <p>59:5 Q. I think I forgot to ask you at the very</p> <p>59:6 beginning, are you board certified?</p> <p>59:7 A. Yes, I am.</p> <p>59:8 Q. And by what board are you certified?</p> <p>59:9 A. American Board of Radiology.</p>	03_20_18 combo FINAL5.60
60:4 - 60:12	<p>Kang, Brandon 06-15-2017 (00:00:25)</p> <p>60:4 Prior to your deposition today, did you have</p>	03_20_18 combo FINAL5.61

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60:5 any contact with either Mr. Roll, Ms. Lourie, or
60:6 anyone from their office?

60:7 A. Yes.

60:8 Q. Okay. And did you meet with them?

60:9 A. Yes.

60:10 Q. When did you meet with them?

60:11 A. Briefly before the meeting today, and a

60:12 couple weeks ago with Robin.

61:21 - 62:14

Kang, Brandon 06-15-2017 (00:00:41)

03_20_18 combo FINAL5.62

61:21 Q. And were you paid for your time or do you

61:22 expect to be paid for your time for that meeting?

61:23 A. Yes.

61:24 Q. And how much have you been asked to be paid

61:25 for your time for the meeting with Ms. Lourie two

62:1 weeks ago?

62:2 A. \$500 an hour.

62:3 Q. And how long did you meet with Ms. Lourie

62:4 today?

62:5 A. Probably another 45 minutes to an hour

62:6 before.

62:7 Q. And in the meeting with Ms. Lourie today,

62:8 did -- let me back up.

62:9 Do you expect to be paid for your time in

62:10 meeting with Ms. Lourie today?

62:11 A. Yes.

62:12 Q. And do you expect to be paid at the same rate

62:13 of \$500 an hour?

62:14 A. Yes.

68:23 - 69:22

Kang, Brandon 06-15-2017 (00:01:07)

03_20_18 combo FINAL5.63

68:23 Q. Mr. Roll asked you a series of questions

68:24 towards the end of his questions to you about "were

68:25 you told," "did you know." Do you remember those

69:1 kinds of questions --

69:2 A. Uh-huh. Yes.

69:3 Q. -- with percentages and rates?

69:4 A. Yes.

69:5 Q. Okay. He did not provide you with any

69:6 documents or any information to substantiate those

69:7 percentages or rates, did he?

69:8 A. Not to me, no.

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69:9 Q. Okay. So when you answered those questions,
 69:10 saying that's information you would want to know, you
 69:11 don't know whether the percentages or rates stated by
 69:12 Mr. Roll are accurate or correct, do you?
 69:13 A. Right. But he was asking me if I knew it was
 69:14 this, if it was, then I would -- then I responded to
 69:15 that.

69:16 Q. Those were hypotheticals, right?

69:17 A. Yes.

69:18 Q. And those are hypotheticals for which he
 69:19 provided you no basis or evidence of the rates or
 69:20 complication, correct?

69:21 A. Correct, because I have no evidence of that
 69:22 on paper, no.

72:25 - 73:5

Kang, Brandon 06-15-2017 (00:00:09)

03_20_18 combo FINAL5.64

72:25 Q. You agree with me that IVC filters can save
 73:1 lives, don't you?

73:2 A. That's a correct statement. I agree.

73:3 Q. In fact, you have made that statement
 73:4 publicly, haven't you?

73:5 A. I have.

80:7 - 80:8

Kang, Brandon 06-15-2017 (00:00:07)

03_20_18 combo FINAL5.65

80:7 Q. Okay. What percentage of your practice today
 80:8 involves implanting or retrieving IVC filters?

81:8 - 82:10

Kang, Brandon 06-15-2017 (00:01:49)

03_20_18 combo FINAL5.66

81:8 Q. Is it less than five percent of the
 81:9 procedures you perform on a regular basis?

81:10 A. Yes.

81:11 Q. Prior to retrieving Ms. Booker's filters --

81:12 Ms. Booker's filter, I apologize, you were aware of
 81:13 complications and risks that come with IVC filters,
 81:14 were you not?

81:15 A. Yes.

81:16 Q. And you were aware that migration,
 81:17 specifically caudal migration, is a complication that
 81:18 can occur with retrievable IVC filters, were you not?

81:19 A. Yes.

81:20 Q. You were also aware that fracture was a risk
 81:21 that could occur with IVC filters, were you not?

81:22 A. Correct.

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81:23 Q. And you also were aware that perforation or
81:24 penetration of the vena cava was a complication that
81:25 could occur with IVC filters, were you not?

82:1 A. Yes.

82:2 Q. Prior to retrieving Ms. Booker's filter, had
82:3 you retrieved other filters that had fractured?

82:4 A. Yes, I have.

82:5 Q. Had you retrieved other filters that had
82:6 migrated caudally?

82:7 A. Yes.

82:8 Q. Had you retrieved other filters that had
82:9 perforated the IVC?

82:10 A. Yes.

83:18 - 83:22

Kang, Brandon 06-15-2017 (00:00:12)

03_20_18 combo FINAL5.67

83:18 Q. Ms. Booker is the
83:19 one and only patient in which you have attempted to
83:20 retrieve any fragment of an IVC filter from any
83:21 portion of the heart; is that right?

83:22 A. Of the heart, correct.

86:20 - 86:23

Kang, Brandon 06-15-2017 (00:00:12)

03_20_18 combo FINAL5.68

86:20 Q. In fact, that's the x-ray that you ordered
86:21 after Ms. Booker was referred to you but prior to
86:22 performing the retrieval procedure; is that correct?

86:23 A. Yes, it was.

89:12 - 89:22

Kang, Brandon 06-15-2017 (00:00:21)

03_20_18 combo FINAL5.69

89:12 Q. Was the leg that was penetrating -- that you
89:13 believe was penetrating the IVC and potentially
89:14 penetrating the abdominal aorta, was that an intact
89:15 leg or was that one of the -- was that the fractured
89:16 leg?

89:17 A. That was the fractured leg.

89:18 Q. Okay. And you were able to successfully
89:19 retrieve that leg?

89:20 A. Yes.

89:21 Q. Is that right?

89:22 A. Yes, ma'am.

90:13 - 91:3

Kang, Brandon 06-15-2017 (00:00:38)

03_20_18 combo FINAL5.70

90:13 the concerns of the now we
90:14 know fragment penetrating the abdominal aorta, you
90:15 were able to remedy that, correct?

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90:16 A. Correct.

90:17 Q. And because you were able to remedy that and

90:18 retrieve that fill -- that fragment, you don't expect

90:19 her to have any further complications from that, do

90:20 you?

90:21 A. From the puncture in the aorta?

90:22 Q. Yes.

90:23 A. No.

90:24 Q. Okay. Did you look at that fractured strut

90:25 when you retrieved it?

91:1 A. Yes.

91:2 Q. And was it a full leg?

91:3 A. I believe it was the entire leg, yes.

96:14 - 96:19

Kang, Brandon 06-15-2017 (00:00:14)

03_20_18 combo FINAL5.72

96:14 Q. But you, Dr. Kang --

96:15 A. Yes.

96:16 Q. -- have not made any recommendation to

96:17 Ms. Booker relating to the fragment that remains in

96:18 her IVC, have you?

96:19 A. No.

98:13 - 98:17

Kang, Brandon 06-15-2017 (00:00:17)

03_20_18 combo FINAL5.73

98:13 Q. Okay. But you did not refer Ms. Booker to

98:14 another interventional radiologist or to a vascular

98:15 surgeon, you made no recommendation relating to the

98:16 fragment that remains in the IVC; is that right?

98:17 A. Yes.

98:18 - 98:23

Kang, Brandon 06-15-2017 (00:00:17)

03_20_18 combo FINAL5.74

98:18 Q. And why was that? Why did you not make a

98:19 recommendation for further treatment?

98:20 A. Like I said, from my standpoint, once

98:21 cardiology and cardiothoracic surgery, they basically

98:22 take over the care, and she was, I mean, in essence,

98:23 almost discharged from my practice and my care.

100:1 - 100:19

Kang, Brandon 06-15-2017 (00:00:46)

03_20_18 combo FINAL5.76

100:1 Q. And the ER doctor, in performing his

100:2 examination and evaluation of Ms. Booker's condition,

100:3 he ordered a CT scan, correct?

100:4 A. Yes.

100:5 Q. And the radiologist reading the CT scan, as

100:6 we've talked about, noted the filter, correct?

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	100:7 A. Yes.	
	100:8 Q. And in fact, it was -- and by noting the	
	100:9 filter, he enabled the ER doctor to fully evaluate his	
	100:10 course of treatment and what was necessary for	
	100:11 Ms. Booker; is that right?	
	100:12 A. Yes.	
	100:13 Q. Okay. And that's what a diagnostic	
	100:14 radiologist does, correct?	
	100:15 A. Yes.	
	100:16 Q. They look at what they are asked to look at,	
	100:17 but they also should report incidental findings,	
	100:18 correct?	
	100:19 A. Correct.	
102:18 - 102:23	Kang, Brandon 06-15-2017 (00:00:16)	03_20_18 combo FINAL5.77
	102:18 In none of the reports relating to the filter	
	102:19 is there any indication, either by you or by the	
	102:20 diagnostic radiologist, that the filter had migrated;	
	102:21 is that right?	
	102:22 A. We don't know if it's potentially migrated	
	102:23 because we don't know where it was initially placed.	
103:5 - 103:14	Kang, Brandon 06-15-2017 (00:00:29)	03_20_18 combo FINAL5.78
	103:5 Q. Dr. Kang, you cannot	
	103:6 testify under oath whether Ms. Booker's filter had	
	103:7 migrated or not, can you?	
	103:8 A. Off of imaging that we got at Gwinnett	
	103:9 Medical System, no.	
	103:10 Q. So when you were asked questions about caudal	
	103:11 migration or migration of her filter, you don't know	
	103:12 whether that is a complication of Ms. Booker's filter	
	103:13 or not, do you?	
	103:14 A. No.	
108:21 - 109:6	Kang, Brandon 06-15-2017 (00:00:20)	03_20_18 combo FINAL5.79
	108:21 Q. Dr. Kang, what does your report state	
	108:22 starting on the bottom of the first page with the	
	108:23 sentence that begins "Next"?	
	108:24 A. "Next, a loop snare was maneuvered to the	
	108:25 appropriate level and the filter was successfully	
	109:1 snared."	
	109:2 It doesn't say in a single attempt or	
	109:3 multiple attempts. It was removed.	

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109:24 - 110:9	<p>109:4 Q. Okay. And then it says: "The filter, snare 109:5 and sheath were removed." Correct? 109:6 A. Yes.</p> <p>Kang, Brandon 06-15-2017 (00:00:34)</p> <p>109:24 Q. Your second portion of your procedure 109:25 was done through the femoral vein, correct? 110:1 A. Correct. 110:2 Q. Okay. So you made another puncture you had 110:3 already prepped her for, I understand all that, and 110:4 that was the attempt at first to remove the entire leg 110:5 that had -- correct? 110:6 A. Yes. 110:7 Q. Okay. And you were successful in retrieving 110:8 the entire leg? 110:9 A. Yes.</p>	03_20_18 combo FINAL5.80
110:16 - 110:22	<p>Kang, Brandon 06-15-2017 (00:00:14)</p> <p>110:16 Q. You didn't leave any portion of that 110:17 leg in Ms. Booker, did you? 110:18 A. Not that I'm -- no, not that I could see 110:19 fluoroscopically, no. 110:20 Q. And you don't have any concern that a portion 110:21 of that is somewhere that you missed? 110:22 A. No.</p>	03_20_18 combo FINAL5.81
111:13 - 111:17	<p>Kang, Brandon 06-15-2017 (00:00:11)</p> <p>111:13 Q. And were you able to lasso the 111:14 remaining fragment, or were you ever able to get the 111:15 loop around it? 111:16 A. I was never able to get the loop around it to 111:17 grab.</p>	03_20_18 combo FINAL5.82
111:18 - 111:24	<p>Kang, Brandon 06-15-2017 (00:00:13)</p> <p>111:18 Q. Was that remaining fragment that you 111:19 were not able to retrieve, was it endothelialized into 111:20 the wall of the IVC? 111:21 A. I don't know. 111:22 Q. Could that have been a reason why you 111:23 couldn't get it? 111:24 A. That's a possibility, yes.</p>	03_20_18 combo FINAL5.83
120:4 - 120:9	<p>Kang, Brandon 06-15-2017 (00:00:12)</p> <p>120:4 Q. And then your report says, and then 120:5 we'll talk about it: "Multiple attempts at capturing</p>	03_20_18 combo FINAL5.84

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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	120:6 the filter fragment in the right ventricle was 120:7 unsuccessful." 120:8 Did I read that correctly? 120:9 A. You did.	
120:11 - 120:13	Kang, Brandon 06-15-2017 (00:00:08) 120:11 Do you recall in this portion of 120:12 your procedure how many attempts you made at capturing 120:13 the filter fragment	03_20_18 combo FINAL5.85
120:13 - 120:21	Kang, Brandon 06-15-2017 (00:00:13) 120:13 in the 120:14 right ventricle? 120:15 A. I don't -- I can't -- I'd be guessing. 120:16 Q. More than one? 120:17 A. More than one. 120:18 Q. Probably -- 120:19 A. Probably less -- probably less than 10. 120:20 Q. Okay. More than five? 120:21 A. Probably right around five.	03_20_18 combo FINAL5.86
121:11 - 122:18	Kang, Brandon 06-15-2017 (00:01:19) 121:11 either in this approach or in the last 121:12 approach, you put the sheath through the tricuspid 121:13 valve; is that right? 121:14 A. Uh-huh. Yes. 121:15 Q. Okay. When the sheath was only in the right 121:16 atrium -- and again, that -- I'm -- as it report -- as 121:17 it indicates in your portion 3 of your report, what 121:18 were -- you had a wire or your -- with your lasso or 121:19 your snare on it going into the right ventricle, 121:20 correct? 121:21 A. Yeah. So probably a little catheter was over 121:22 a wire, got into the ventricle. 121:23 Q. Okay. 121:24 A. And then the wire comes out, then the snare 121:25 goes in through that little catheter and the snare 122:1 comes out. 122:2 Q. Okay. So what was going -- when the sheath 122:3 was in the right atrium only, what was going through 122:4 the tricuspid valve, the catheter? 122:5 A. A catheter and a wire. 122:6 Q. Okay. And --	03_20_18 combo FINAL5.87

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	122:7 A. And eventually the snare, which is inside the 122:8 catheter. 122:9 Q. Okay. Okay. And did you go through the 122:10 tricuspid valve -- when you had the sheath in the 122:11 right atrium, did you go -- did you take the catheter 122:12 and the wire through the tricuspid valve more than one 122:13 time? 122:14 A. Uh-huh. 122:15 Q. So you were going in -- 122:16 A. Yes. 122:17 Q. -- and out of the tricuspid valve? 122:18 A. Probably a few times.	
122:18 - 122:24	Kang, Brandon 06-15-2017 (00:00:20) 122:18 A. Probably a few times. I mean, some -- a lot 122:19 of it was inside the ventricle with a catheter, and 122:20 with the snare going in and out with the catheter 122:21 still in the tricuspid valve, but I'm sure -- I mean, 122:22 I can't -- I mean, that's a beating organ sometimes. 122:23 I'm sure the catheter may have slipped backwards and 122:24 then we may have readvanced it. That's hard to say.	03_20_18 combo FINAL5.88
123:10 - 123:15	Kang, Brandon 06-15-2017 (00:00:16) 123:10 Q. did you do anything to protect the 123:11 tricuspid valve from the wire or the catheter? 123:12 A. No. 123:13 the time, go into the pulmonary arteries all the time 123:14 for thrombolysis, so it's not uncommon to go put 123:15 catheters and wires through the tricuspid valve.	03_20_18 combo FINAL5.89
129:11 - 130:17	Kang, Brandon 06-15-2017 (00:01:25) 129:11 Q. And you went into the right atrium; is that 129:12 right? 129:13 A. Yes. 129:14 Q. And then through the tricuspid valve and into 129:15 the right ventricle; is that right? 129:16 A. Yes. 129:17 Q. Okay. And to finish your note: "Multiple 129:18 attempts at capturing the cardiac filter fragment was 129:19 again unsuccessful." 129:20 Did I read that correctly? 129:21 A. Correct. 129:22 Q. Okay. And you used that phrase again,	03_20_18 combo FINAL5.90

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129:23 "multiple"?

129:24 A. Yes.

129:25 Q. Is that some -- last time, in the third

130:1 portion, you testified that multiple was somewhere

130:2 between five and 10. Would it be the same thing here?

130:3 A. Possibly. I don't -- I just -- I don't --

130:4 it's hard to define multiple or how many because, I

130:5 mean, if the lasso or if the snare goes out once and

130:6 back, is that one, two? I mean -- so it's kind of

130:7 hard to quantify the number.

130:8 Q. Okay. And during this portion of the

130:9 procedure, did you have the sheath through the

130:10 tricuspid valve and into the right ventricle, or was

130:11 the sheath in the right atrium and the catheter and

130:12 the wire and the snare going into the right ventricle,

130:13 or both?

130:14 A. Probably more so in the right ventricle.

130:15 Q. Okay. You put the whole sheath into the

130:16 right ventricle?

130:17 A. Uh-huh.

134:4 - 134:7

Kang, Brandon 06-15-2017 (00:00:10)

03_20_18 combo FINAL5.91

134:4 Q. So you understand and agree that the -- a

134:5 portion of her tricuspid valve was damaged or torn

134:6 during the procedure that you performed, correct?

134:7 A. Yes.

135:1 - 135:5

Kang, Brandon 06-15-2017 (00:00:17)

03_20_18 combo FINAL5.92

135:1 Q. At any point after learning that there was an

135:2 issue with the tricuspid valve, did you have any

135:3 conversation with Ms. Booker?

135:4 A. Directly saying that -- no, I don't think so,

135:5 not specifically regards to that.

138:22 - 138:24

Kang, Brandon 06-15-2017 (00:00:05)

03_20_18 combo FINAL5.93

138:22 A. Well, I'm not saying I -- well, I was using

138:23 the term "lasso" because the snare is like a lasso.

138:24 It's a loop.

143:23 - 144:2

Kang, Brandon 06-15-2017 (00:00:13)

03_20_18 combo FINAL5.94

143:23 You have not made a recommendation to

143:24 Ms. Booker or any of her treating physicians that she

143:25 have a referral to someone else to do a different

144:1 technique to try to retrieve the fragment in her IVC?

Page/Line	Source	ID
146:10 - 146:18	<p>144:2 A. Have not.</p> <p>Kang, Brandon 06-15-2017 (00:00:34)</p> <p>146:10 Q. Prior to performing the procedure that you</p> <p>146:11 performed in July of 2014, did you consult with any</p> <p>146:12 other interventional radiologists?</p> <p>146:13 A. No.</p> <p>146:14 Q. In your group at Gwinnett in July of 2014,</p> <p>146:15 how many interventional radiologists were there?</p> <p>146:16 A. Four or five.</p> <p>146:17 Q. And you didn't consult with any of them?</p> <p>146:18 A. No.</p>	03_20_18 combo FINAL5.95
161:23 - 162:10	<p>Kang, Brandon 06-15-2017 (00:00:40)</p> <p>161:23 Q. So would you state whether or not you have</p> <p>161:24 experience in manipulating instruments, catheters,</p> <p>161:25 wires, other instruments, in the hearts of patients,</p> <p>162:1 including the right atrium --</p> <p>162:2 A. Right.</p> <p>162:3 Q. -- the tricuspid valve and right ventricle?</p> <p>162:4 A. A lot of experience of putting catheters,</p> <p>162:5 sheaths, thrombectomy devices, all through the heart,</p> <p>162:6 through the right ventricle.</p> <p>162:7 Q. Okay. And would you state whether or not you</p> <p>162:8 are experienced with and learned in techniques to</p> <p>162:9 avoid as much as possible damage to a tricuspid valve</p> <p>162:10 during procedure maneuvers?</p>	03_20_18 combo FINAL5.96
162:13 - 162:13	<p>Kang, Brandon 06-15-2017 (00:00:01)</p> <p>162:13 A. Yes.</p>	03_20_18 combo FINAL5.97
163:14 - 163:20	<p>Kang, Brandon 06-15-2017 (00:00:14)</p> <p>163:14 Q. And in fact, you are, just to be</p> <p>163:15 clear, you are the head of the Department of</p> <p>163:16 Diagnostic Imaging?</p> <p>163:17 A. I'm the Chief of Radiology.</p> <p>163:18 Q. Okay.</p> <p>163:19 A. That's the diagnostic part, and I'm also the</p> <p>163:20 Director of the interventional section as well.</p>	03_20_18 combo FINAL5.98
164:21 - 164:25	<p>Kang, Brandon 06-15-2017 (00:00:12)</p> <p>164:21 Q. And do you enjoy any certification status</p> <p>164:22 with vascular interventional radiology?</p> <p>164:23 A. Right. I have a Certificate of</p> <p>164:24 Qualification, which is a subspecialty of diagnostic</p>	03_20_18 combo FINAL5.99

03_20_18 combo FINAL5-Kang 06-15-17 Booker Depo Designations FINAL5

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165:1 - 165:4

164:25 radiology, the interventional.

Kang, Brandon 06-15-2017 (00:00:10)

03_20_18 combo FINAL5.100

165:1 Q. And also I see on your CV you list Consumers

165:2 Research Council, America's Top Radiologists,

165:3 2007-2008.

165:4 A. Yes.

Plaintiffs Designations = 00:17:47

Defense Designations = 00:14:40

Plaintiffs And Defense Designations = 00:01:18

Total Time = 00:33:45**Documents Shown**

2350_MEDICAL

2368_MR

EXHIBIT G

Designation Run Report

Harvey 06-20-17 Booker Depo Designations Final V3.1

Harvey, Richard 06-20-2017

Plaintiffs Designations 00:20:32

Defense Designations 00:09:20

Total Time 00:29:52



03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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22:6 - 22:13	Harvey, Richard 06-20-2017 (00:00:29) 22:6 Q. Based upon the examination of Ms. Booker in 22:7 your office on July 8, 2014, based upon the 22:8 cardiovascular consultation which is recorded in 22:9 Exhibit 4, did you and Dr. -- would you state whether 22:10 or not you and Dr. Langford concurred with Dr. Kang's 22:11 plan to attempt to retrieve this fragment from the 22:12 heart using the percutaneous approach? 22:13 A. We encouraged him to attempt that.	03_20_18 combo Final 3_1.1 _3_HARVEY.1.1 _3_HARVEY.2
22:18 - 23:1	Harvey, Richard 06-20-2017 (00:00:19) 22:18 Q. Would you state whether or not 22:19 there was any guarantee that the percutaneous approach 22:20 was, in fact, going to be successful on retrieving the 22:21 fragment from the heart? 22:22 A. No, we thought it was -- I'm not an 22:23 interventionalist but our take on it was it was low 22:24 probability, but we thought it was worth the -- it 22:25 was certainly worth the effort because the risk is so 23:1 much less than what we do.	03_20_18 combo Final 3_1.2 clear
23:25 - 24:3	Harvey, Richard 06-20-2017 (00:00:16) 23:25 Q. What was the plan between Dr. Kang and 24:1 you and Dr. Langford with regard to whether there 24:2 would be any involvement of a cardiothoracic surgeon 24:3 during the percutaneous approach?	03_20_18 combo Final 3_1.3
24:5 - 24:17	Harvey, Richard 06-20-2017 (00:00:44) 24:5 A. My best recollection of that is that 24:6 Dr. Langford and I had been discussing this over and 24:7 over again, and he was talking with Dr. Kang most of 24:8 the time during all this, but most of the time I was 24:9 sitting there when he was talking to him, but we were 24:10 going to -- there are two of us there. We can run 24:11 two rooms simultaneously, which means no one would be 24:12 available if something happened. So we intentionally 24:13 made sure that only one of us was in surgery during 24:14 the period of time that he would be attempting to do 24:15 this, and so one would be available if there were 24:16 problems or issues where the patient would have to go 24:17 to surgery.	03_20_18 combo Final 3_1.4
27:1 - 27:5	Harvey, Richard 06-20-2017 (00:00:15) 27:1 Q. There you go. So I've handed you a document	03_20_18 combo Final 3_1.5

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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27:2 that I marked as Exhibit 5. Would you identify what
27:3 this document is?

_4_HARVEY.1.2

27:4 A. This is a consult note from when we formally
27:5 consulted on the patient in the hospital.

30:1 - 30:2

Harvey, Richard 06-20-2017 (00:00:08)

03_20_18 combo Final 3_1.6

30:1 As of the date of your

_4_HARVEY.1.3

30:2 consult on July 27, 2014, were you aware

30:4 - 30:19

Harvey, Richard 06-20-2017 (00:00:46)

03_20_18 combo Final 3_1.7

30:4 whether Dr. Kang had been successful in

30:5 retrieving the filter fragment from the right

30:6 ventricle in Ms. Booker's heart?

30:7 A. Yes. We knew he had not been able to do

30:8 that.

30:9 Q. And what was your understanding as to why you
30:10 then were called in on a consult?

clear

30:11 A. Well, it's two reasons: It was because the

30:12 device or the piece, fragment of the device, had not

30:13 been able to be retrieved, and, you know, quite

30:14 frankly, one of the reasons that we pushed him to do

30:15 this interventionally is because we were going to

30:16 retrieve it surgically if he couldn't, either way.

30:17 And so in addition to that, by this time the patient

30:18 had developed tricuspid regurgitation, which was from

30:19 the attempt to retrieve the device.

30:22 - 30:25

Harvey, Richard 06-20-2017 (00:00:12)

03_20_18 combo Final 3_1.8

30:22 Would you state whether or not you were aware

30:23 that Dr. Kang, during the July 23 procedure, had

30:24 inadvertently injured the tricuspid valve during his

30:25 percutaneous attempt?

31:2 - 31:6

Harvey, Richard 06-20-2017 (00:00:09)

03_20_18 combo Final 3_1.9

31:2 A. We knew that from the echo after the

31:3 procedure.

31:4 Q. All right. Do you have any criticism of

31:5 Dr. Kang for inadvertently injuring the valve during

31:6 his percutaneous attempt?

31:8 - 31:17

Harvey, Richard 06-20-2017 (00:00:28)

03_20_18 combo Final 3_1.10

31:8 A. No, because we -- we know that's a

31:9 possibility. We thought the risk of him -- all these

31:10 things are something that we can fix if we're going

31:11 there. We were going to go there. So we had asked

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31:12 him to be aggressive with trying to retrieve this
 31:13 device.
 31:14 So the only thing that would have kept us
 31:15 from operating on the patient is if he had been able
 31:16 to retrieve the fragment and not have any issues with
 31:17 the tricuspid valve.

31:18 - 32:3

Harvey, Richard 06-20-2017 (00:00:40)

03_20_18 combo Final 3.1.11

31:18 Q. And based upon your examination
 31:19 and diagnostic studies, based upon your understanding
 31:20 of the history of Ms. Booker, and based upon your
 31:21 previous contact with Ms. Booker, would you state
 31:22 whether or not you formed a plan as far as what your
 31:23 medical and/or surgical services were going to be?
 31:24 A. We did. After the procedure, the fragment
 31:25 was still there, there was tricuspid regurgitation,
 32:1 so we decided that we needed to do surgery, and so we
 32:2 did, you know, not -- fairly expeditiously, but it
 32:3 wasn't emergent surgery, but we did it fairly soon.

32:4 - 32:20

Harvey, Richard 06-20-2017 (00:00:59)

03_20_18 combo Final 3.1.12

32:4 Q. would you explain to the jury
 32:5 why you decided not to just leave the fragment -- the
 32:6 filter fragment in the right ventricle of Ms. Booker's
 32:7 heart?
 32:8 A. You know, this fragment has risks associated
 32:9 with it. We suspected -- we didn't know, but we
 32:10 suspected it was embedded, but we've all -- everybody
 32:11 that does this have seen devices that have penetrated
 32:12 the ventricle. The right ventricle is -- you know,
 32:13 we have two ventricles, the left and the right. The
 32:14 left ventricle is a very thick muscle. The right
 32:15 ventricle is very thin. The left ventricle is what
 32:16 generates the 120/80 that is our blood pressure. The
 32:17 right ventricle generates 25/15. It's thin muscle.
 32:18 And so we felt that she was at risk for
 32:19 perforation and that the device needed to be
 32:20 retrieved.

33:13 - 34:15

Harvey, Richard 06-20-2017 (00:01:35)

03_20_18 combo Final 3.1.13

33:13 Q. Let me ask you this, Doctor.
 33:14 Would it matter whether or not the fragment had, in
 33:15 whole or in part, endothelialized as far as your

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33:16 decision that the fragment posed a risk to the patient
33:17 and needed to be removed?

33:18 A. No. I have experienced issues with
33:19 perforations many times through the years. If you
33:20 wait till something perforates, then the patient is
33:21 probably going to die, and the longer it's been in
33:22 there, the stiffer it gets, the muscle around it
33:23 stiffens, it kind of forms a fulcrum, it can push
33:24 easier, or the cord thickens if it's in a cord.
33:25 The tissue of our body responds to something
34:1 that's foreign, and it does with an inflammation and
34:2 thickening, and it can lead to problems down the road
34:3 that can be lethal. I've had to deal with it in the
34:4 middle of the night, in the middle of the day too
34:5 many times through the years, in different forms, in
34:6 different figures, different devices, pacemaker leads
34:7 that have been in for a long time, all of these
34:8 things. When they perforate, you bleed and you die
34:9 if you can't get to an operating room very
34:10 expeditiously.
34:11 So it makes no sense to somebody that's seen
34:12 that side of it to leave it hoping nothing ever
34:13 happens, because if it does, then unless they are in
34:14 a hospital when it does, they are likely going to
34:15 die.

34:18 - 35:6

Harvey, Richard 06-20-2017 (00:00:44)

03_20_18 combo Final 3.1.14

34:18 Q. And, Doctor, could you tell the jury then
34:19 what your plan was as far as the type of surgical
34:20 procedure that you were going to perform on Ms. Booker
34:21 to remove this heart -- this filter fragment?
34:22 A. Because of what was involved, this could be
34:23 done minimally invasively.
34:24 that, from the outset, Dr. Langford and I were
34:25 communicating this together. We were talking about
35:1 approaches. I do minimally invasive surgery, so we
35:2 could do this with what's called minimally invasive
35:3 surgery rather than a full open sternotomy, or
35:4 dividing the breastbone, the typical heart incision
35:5 that you see. This lends itself to being done
35:6 minimally invasively.

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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35:7 - 35:9	Harvey, Richard 06-20-2017 (00:00:08) 35:7 Q. Okay. Now, let me ask you about the term 35:8 "minimally invasive." Does minimally invasive mean 35:9 that this was not open-heart surgery?	03_20_18 combo Final 3.1.15
35:11 - 35:16	Harvey, Richard 06-20-2017 (00:00:19) 35:11 A. No. This is -- this is open-heart surgery. 35:12 The risks are the same, the risks of dying are the 35:13 same. The difference is cosmesis and then 35:14 restrictions after the surgery. So there is less of 35:15 a scar and you're not restricted in what you can do 35:16 for as long after the surgery.	03_20_18 combo Final 3.1.16
41:16 - 41:20	Harvey, Richard 06-20-2017 (00:00:23) 41:16 Q. I'm going to mark as Exhibit 7 a 41:17 document. If you could just identify that for me, 41:18 please, sir. 41:19 A. This is the operative report from the surgery 41:20 on Ms. Booker on July -- let's see -- July 28, 2014.	03_20_18 combo Final 3.1.17 _1_2361_HARVEY.1.1 _1_2361_HARVEY.1.2
42:2 - 42:11	Harvey, Richard 06-20-2017 (00:00:31) 42:2 Let's first start, so the date of the 42:3 procedure was what? 42:4 A. July 28, 2014. 42:5 Q. Okay. And let me ask you this while we're at 42:6 it and while we're talking about this procedure. Do 42:7 you have an opinion as to whether or not you would 42:8 have performed this surgical procedure -- this 42:9 open-heart surgical procedure to retrieve the filter 42:10 fragment from the right ventricle even had the 42:11 tricuspid valve not been injured?	03_20_18 combo Final 3.1.18 _1_2361_HARVEY.1.4
42:13 - 42:20	Harvey, Richard 06-20-2017 (00:00:28) 42:13 A. That was our plan all along. I think I've 42:14 stated that several times. Our plan was to remove 42:15 the foreign device from inside the heart, and we were 42:16 encouraging, pushing, Dr. Kang to try to do it 42:17 minimally invasive -- or do it, excuse me, 42:18 interventionally, if possible, but either way, our 42:19 plan was to remove the foreign body out of the heart 42:20 muscle.	03_20_18 combo Final 3.1.19
49:10 - 49:22	Harvey, Richard 06-20-2017 (00:00:34) 49:10 Q. What is the pericardium? 49:11 A. The pericardium is the sac the heart lives	03_20_18 combo Final 3.1.25

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49:12 in.

49:13 Q. All right.

49:14 A. And it's a fibrous tough structure.

49:15 Q. And how do you open it?

49:16 A. Cut it usually with a Bovie, with a

49:17 electrocautery device, and we have to open it the

49:18 full length from the -- I'm trying to think in

49:19 nonmedical terms -- from the pericardium what's

49:20 called cephalad, toward the head, and then to the

49:21 base where it's near the diaphragm or the lower part

49:22 of the body.

50:16 - 50:18

Harvey, Richard 06-20-2017 (00:00:06)

03_20_18 combo Final 3.1.68

50:16 Q. I'm sorry. So we've gotten to the point

50:17 where you've gone through the sac surrounding the

50:18 heart,

50:23 - 51:8

Harvey, Richard 06-20-2017 (00:00:39)

03_20_18 combo Final 3.1.26

50:23 A. There is a solution called cardioplegia.

50:24 Potassium -- I mean, potassium is what they use

50:25 for -- what would be the correct term for that? When

51:1 someone dies by lethal injection, it's potassium that

51:2 does it. Okay? Because it makes your heart stop.

51:3 What we do, in cardiac surgery, we're doing

51:4 it locally confined to the heart. Since we have the

51:5 crossclamp on the heart, we then can inject a

51:6 solution that goes through the coronary arteries,

51:7 throughout the heart muscle that's high in potassium

51:8 that makes the heart stop beating.

51:12 - 51:17

Harvey, Richard 06-20-2017 (00:00:14)

03_20_18 combo Final 3.1.27

51:12 Q. And why was it necessary to stop Ms. Booker's

51:13 heart from beating during this procedure?

51:14 A. If you don't stop the heart from beating,

51:15 then blood will be in the way and the heart will be

51:16 moving and you can't work, you can't do the things

51:17 you need to do.

53:15 - 53:22

Harvey, Richard 06-20-2017 (00:00:22)

03_20_18 combo Final 3.1.28

53:15 Q. Ask it another way: Would you state whether

53:16 or not you were able to successfully remove this metal

53:17 fragment from Ms. Booker's body?

53:18 A. We did.

53:19 Q. And what was your understanding as you were

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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53:20 performing your surgical services on Ms. Booker of
53:21 where this metal came from?

54:2 - 54:10 53:22 A. From a cava filter in her inferior vena cava.

Harvey, Richard 06-20-2017 (00:00:42)

03_20_18 combo Final 3.1.29

_1_2364_HARVEY.1.2

54:2 Q. Now, I'll mark as Exhibit 8 a pathology
54:3 report, and ask you to identify this report and what
54:4 this report refers to.

_1_2364_HARVEY.1.3

54:5 A. Well, when we remove anything from the body
54:6 during surgery, we generally send it to pathology.

54:7 Q. Is that what this is?

54:8 A. That's what -- this is the report from
54:9 sending this metal fragment to the pathologist
54:10 department.

54:23 - 55:3 **Harvey, Richard 06-20-2017 (00:00:13)**

03_20_18 combo Final 3.1.30

54:23 Q. would you state whether or not
54:24 this piece of metal as described in the pathology
54:25 report is the piece of a metal fragment that you
55:1 retrieved from the right ventricle of Ms. Booker's
55:2 heart?

55:3 A. That is.

58:23 - 59:10 **Harvey, Richard 06-20-2017 (00:00:51)**

03_20_18 combo Final 3.1.31

58:23 Q. I've marked as Exhibit 9 a document which I'd
58:24 like you to identify for us, please, sir.

58:25 A. This is the cardiopulmonary perfusion record
59:1 that -- which is -- what that is, is a heart-lung
59:2 machine is run by a specialist called a perfusionist.
59:3 This is the record of their running the heart-lung
59:4 machine during the operation.

59:5 Q. All right. And based upon your review of
59:6 this document, can you tell the jury how long
59:7 Ms. Booker's heart was stopped during your surgical
59:8 procedure which you have described?

59:9 A. It was stopped approximately an
59:10 hour-and-a-half.

61:12 - 61:25 **Harvey, Richard 06-20-2017 (00:00:40)**

03_20_18 combo Final 3.1.69

61:12 Q. Now, you had mentioned earlier
61:13 about having to cut or cauterize through the
61:14 pericardium in order to access the heart.

61:15 A. Right.

61:16 Q. After you're backing out, do you attempt to

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61:17 repair the pericardium, or not?

61:18 A. No, we generally don't close the pericardium,
61:19 because most patients will bleed some after heart
61:20 surgery. We've got drainage tubes in to capture it,
61:21 but if you close the pericardium, they can get
61:22 something called tamponade, which is where you bleed
61:23 outside the heart. It presses on the heart and then
61:24 it can cause you to arrest. So we usually leave the
61:25 pericardium open regardless of the approach.

65:17 - 65:18

Harvey, Richard 06-20-2017 (00:00:08)

03_20_18 combo Final 3.1.33

65:17 Q. I'm going to mark as -- I think we're up to
65:18 11.

65:19 - 66:4

Harvey, Richard 06-20-2017 (00:00:32)

03_20_18 combo Final 3.1.34

65:19 Would you state what Exhibit 11 is?

65:20 A. This is a daily progress note from seeing the
65:21 patient after the surgery.

65:22 Q. This is dated July 30, 2014?

65:23 A. Correct.

65:24 Q. And did you make rounds on the patient that
65:25 day?

66:1 A. I did.

66:2 Q. Now, what was -- in terms of her recovery
66:3 experience or recovery process, did she encounter any
66:4 postoperative bleeding problems?

66:6 - 66:23

Harvey, Richard 06-20-2017 (00:00:57)

03_20_18 combo Final 3.1.35

66:6 A. Well, it's -- you know, one of the
66:7 consequences of the heart-lung machine and heart
66:8 surgery is that you get very diluted. So your, you
66:9 know, your normal red cell levels in your body are
66:10 depleted, as well as usually your platelets after
66:11 heart surgery. So it's not uncommon, even if you
66:12 don't -- even if you don't have significant postop
66:13 bleeding, like through your chest tubes, which is
66:14 direct surgical bleeding, that you will get anemic.
66:15 You come out of the operation anemic.
66:16 And so transfusion is usually based on
66:17 whether you are anemic to a certain level and/or
66:18 symptoms. So what this record indicates is that the
66:19 patient was hypotensive and anemic with a hematocrit
66:20 of 23.

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66:21 Now, with a hematocrit of 23 we would watch
 66:22 it if she weren't hypotensive, but she's tachycardic
 66:23 and hypotensive, so we gave her blood.

66:25 - 67:10

Harvey, Richard 06-20-2017 (00:00:29)

03_20_18 combo Final 3.1.36

66:25 Q. Okay. And in response to her anemia as
 67:1 reflected in your progress note, what was your
 67:2 therapeutic response?

67:3 A. Blood transfusion.

67:4 Q. Are there any risks associated with blood
 67:5 transfusions?

67:6 A. Yes, there is. The most significant ones are
 67:7 the ones that everybody discusses, which is hepatitis
 67:8 and AIDS, but there is adverse reactions. It's not
 67:9 your blood, so there are risks with blood
 67:10 transfusions.

72:14 - 72:18

Harvey, Richard 06-20-2017 (00:00:07)

03_20_18 combo Final 3.1.37

72:14 the x-ray showed that it

72:15 had essentially resolved?

72:16 A. Yeah. Sometimes these will go away on their
 72:17 own and it's a judgment call as to when you intervene
 72:18 and not.

73:8 - 74:1

Harvey, Richard 06-20-2017 (00:01:14)

03_20_18 combo Final 3.1.38

73:8 this is dated September 9, 2014. Is this an
 73:9 office visit?

73:10 A. This is an office visit.

73:11 Q. Does this appear to be the last time that you
 73:12 saw Ms. Booker in your office?

73:13 A. This does.

73:14 Q. All right. And if you could, just describe
 73:15 generally how she was at this point.

73:16 A. Still fairly typical, other than she was --
 73:17 had a subjective complaint of palpitations, or feeling
 73:18 like that heartbeat was not regular. That's fairly
 73:19 common after heart surgery.

73:20 It appears that her right effusion had
 73:21 resolved. And when it comes to rhythm disturbances,
 73:22 generally cardiology handles that once you get past
 73:23 the nonacute setting.

73:24 So, ultimately, from a wound healing surgical
 73:25 point of view, we released her and everything went

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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74:10 - 74:21

74:1 back to medical management with Dr. Patel.

Harvey, Richard 06-20-2017 (00:00:40)

03_20_18 combo Final 3.1.39

74:10 Q. And then finally, with regard to

74:11 your office records, if you could flip to page 47 in

74:12 the left-hand -- the page numbers on the left-hand

74:13 bottom, and that's a -- it looks like a return to work

74:14 form filled out by your office dated October 13, 2014.

74:15 Is that accurate?

74:16 A. That is.

74:17 Q. And would you just read what it states under

74:18 that status, under "Other"?

74:19 A. Correct. It says return to work half days

74:20 for the month of October, then resume full-time

74:21 beginning November 2014.

75:11 - 75:17

Harvey, Richard 06-20-2017 (00:00:27)

03_20_18 combo Final 3.1.40

75:11 I'd like to just ask you about long-term

75:12 complications of the open-heart surgery that

75:13 Ms. Booker underwent at your hands. Based upon your

75:14 knowledge as a surgeon with regard to long-term

75:15 complications of this surgical procedure, could you

75:16 describe those for the jury, or the potential for the

75:17 complications?

75:19 - 76:5

Harvey, Richard 06-20-2017 (00:00:46)

03_20_18 combo Final 3.1.41

75:19 A. Yeah. The -- early versus late: The most

75:20 common things that happen early after heart surgery

75:21 is atrial fib. It's an arrhythmia that the heart

75:22 gets because everybody has inflammation, pericardial

75:23 inflammation, or the heart sac gets inflamed, the

75:24 heart itself is inflamed. So electricity doesn't

75:25 work as well in wet inflamed tissue as it does in our

76:1 normal situation. So that's very common with valve

76:2 surgeries. The statistics are about 50 percent of

76:3 patients will have arrhythmias, most commonly atrial

76:4 fib. Usually that resolves as the inflammation

76:5 resolves, so it's a period of time.

76:12 - 76:17

Harvey, Richard 06-20-2017 (00:00:14)

03_20_18 combo Final 3.1.42

76:12 Everybody has, generally, a period of time

76:13 where the pain waxes and wanes. It will go -- you

76:14 know, you are now two months out and you think it's

76:15 over or you will turn the wrong way or, you know,

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76:22 - 77:22

76:16 even at night, cough or something and the pain will
76:17 come back for a little while. So that can -- that

Harvey, Richard 06-20-2017 (00:01:26)

03_20_18 combo Final 3_1.43

76:22 Q. Well, let me ask you this. What is post
76:23 -sternotomy pain syndrome?

76:24 A. That's when the nerve -- under each rib there
76:25 is a large nerve, and some patients, no matter what
77:1 you do, can get what's called postthoracotomy pain
77:2 syndrome, and that's where the pain from that
77:3 incision just won't go away.

77:4 Q. All right. And describe for us what
77:5 pericarditis is.

77:6 A. That's inflammation of the heart sac. Every
77:7 patient has that initially after surgery. You can't
77:8 open any body cavity without that area being inflamed
77:9 for a period of time.

77:10 Q. Would you state whether or not pericarditis
77:11 can be a long-term complication?

77:12 A. It can. It's pretty rare but everybody has
77:13 it after surgery, about 20 to 30 percent have
77:14 clinical signs of it after surgery, and then there is
77:15 a small percentage, and I don't know what the number
77:16 is, that can have recurrent problems with that. And
77:17 you can see it de novo, without having surgery as
77:18 well, but surgery can induce that.

77:19 I mean, any time that you cut, you know, do
77:20 whatever to tissue, everybody heals differently,
77:21 everybody responds to it differently, and some people
77:22 have a, you know, a long-term consequence from it.

87:3 - 87:13

Harvey, Richard 06-20-2017 (00:00:21)

03_20_18 combo Final 3_1.44

87:3 Q. You understand that the fragment that you
87:4 retrieved from Ms. Booker was not in her right atrium,
87:5 it was in her right ventricle, correct?

87:6 A. Yeah, I don't -- yeah.

87:7 Q. And anatomically, those are two different
87:8 areas of the heart, correct?

87:9 A. They are.

87:10 Q. Okay. And in fact, you have to go through
87:11 the tricuspid valve to get to the right ventricle,
87:12 correct?

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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88:13 - 88:24	<p>87:13 A. Correct.</p> <p>Harvey, Richard 06-20-2017 (00:00:28)</p> <p>88:13 Q. It's a radiology -- it's a CT CTA of the</p> <p>88:14 heart structure ordered by Dr. Heller. Do you see</p> <p>88:15 that?</p> <p>88:16 A. I do.</p> <p>88:17 Q. And who is Dr. Heller?</p> <p>88:18 A. He is an interventional cardiologist at</p> <p>88:19 Gwinnett Medical Center.</p> <p>88:20 Q. Okay. And was it your understanding that</p> <p>88:21 during her hospitalization and between the procedure</p> <p>88:22 performed by Dr. Kang and the procedure performed by</p> <p>88:23 you, that Ms. Booker was treated by Dr. Heller?</p> <p>88:24 A. Yes.</p>	03_20_18 combo Final 3_1.45
89:10 - 89:18	<p>Harvey, Richard 06-20-2017 (00:00:32)</p> <p>89:10 Q. And his -- the findings of this are</p> <p>89:11 that there was a three -- I can't get it out of my</p> <p>89:12 mouth -- a three-centimeter wire in the right</p> <p>89:13 ventricle with both ends clearly embedded in the right</p> <p>89:14 ventricular base myometrial trabeculation. Correct?</p> <p>89:15 A. Yeah, that's close enough.</p> <p>89:16 Q. Okay. There was a small wire with both ends</p> <p>89:17 embedded in the wall of the right ventricle; is that</p> <p>89:18 right?</p>	03_20_18 combo Final 3_1.46
89:23 - 89:24	<p>Harvey, Richard 06-20-2017 (00:00:02)</p> <p>89:23 A. Yes, no doubt about it, that's exactly what</p> <p>89:24 it says.</p>	03_20_18 combo Final 3_1.47
90:4 - 90:10	<p>Harvey, Richard 06-20-2017 (00:00:18)</p> <p>90:4 Q. So it was not floating, it was clearly</p> <p>90:5 embedded in the wall of the right ventricle?</p> <p>90:6 A. When we saw it, yes.</p> <p>90:7 like this before where this did not end up being the</p> <p>90:8 case, and that's why -- we certainly look at all</p> <p>90:9 these reports but it isn't the Bible when it comes to</p> <p>90:10 this sort of thing.</p>	03_20_18 combo Final 3_1.70
91:1 - 91:11	<p>Harvey, Richard 06-20-2017 (00:00:28)</p> <p>91:1 Q. Throughout your testimony today</p> <p>91:2 you have testified that during Dr. Kang's procedure to</p> <p>91:3 attempt to retrieve the strut from the right</p> <p>91:4 ventricle, the tricuspid valve was damaged. In fact,</p>	03_20_18 combo Final 3_1.48

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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91:5 it was damaged as a result of Dr. Kang going through
 91:6 the tricuspid valve and attempting to retrieve the
 91:7 strut, correct?

91:8 A. Yes.

91:9 Q. Okay. So her tricuspid valve was not damaged
 91:10 prior to the procedure by Dr. Kang, correct?

91:11 A. That's right.

91:12 - 91:22

Harvey, Richard 06-20-2017 (00:00:37)

03_20_18 combo Final 3.1.49

91:12 Q. And would you agree with me that any
 91:13 medical professional who is performing a procedure in
 91:14 the heart that goes through the tricuspid valve should
 91:15 take care to protect that valve as they go in and out
 91:16 of it?

91:17 A. I would agree that you should.

91:18 the time, pacemaker placements and defibrillator
 91:19 placements, so it's not unusual for -- sometimes even
 91:20 when it's not damaged, they will get tricuspid
 91:21 regurgitation from just the lie of the pacemaker
 91:22 lead, so it's something you see.

93:2 - 93:20

Harvey, Richard 06-20-2017 (00:00:55)

03_20_18 combo Final 3.1.50

93:2 Q. And you didn't spread her sternum,
 93:3 correct?

93:4 A. You still spread the ribs.

93:5 Q. Okay. So you would expect her pain to be in
 93:6 the area where you spread it, correct?

93:7 A. It's usually anterior to that. The

93:8 distribution of the nerve goes anterior, but --

93:9 meaning you're not just affecting the nerve where the
 93:10 retractor is. Again, it's depending on the spread.

93:11 Postthoracotomy pain syndromes are more likely after
 93:12 full thoracotomies, rather than small thoracotomies,
 93:13 because you spread further, you affect more ribs and
 93:14 more nerves.

93:15 Q. Okay. And was hers a small thoracotomy?

93:16 A. Right, five centimeters, six centimeters,
 93:17 something like that.

93:18 Q. Did you consider your repair of the tricuspid
 93:19 valve to be a successful repair?

93:20 A. I did.

93:21 - 93:25

Harvey, Richard 06-20-2017 (00:00:12)

03_20_18 combo Final 3.1.51

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93:21 Q. did you or have you

93:22 prescribed any follow-up care for Ms. Booker relating
93:23 to her tricuspid valve?

93:24 A. That's -- you've understood the cardiologists
93:25 will follow that with echo.

94:17 - 94:21

Harvey, Richard 06-20-2017 (00:00:12)

03_20_18 combo Final 3.1.52

94:17 Q. so if Dr. Patel testified

94:18 that the reason why she had to have an open procedure
94:19 was because she had both the torn tricuspid valve and
94:20 the foreign body or the strut in the right ventricle,
94:21 you disagree with that?

95:5 - 95:7

Harvey, Richard 06-20-2017 (00:00:06)

03_20_18 combo Final 3.1.53

95:5 A. I would say that the reason we operated on
95:6 her on that admission on the day that we did was
95:7 because both had occurred.

97:9 - 97:12

Harvey, Richard 06-20-2017 (00:00:11)

03_20_18 combo Final 3.1.54

97:9 Q. You testified that you, as part of your
97:10 surgical procedure, you had to stop Ms. Booker's heart
97:11 and put her on a heart-lung machine, correct?

97:12 A. Correct.

97:23 - 98:2

Harvey, Richard 06-20-2017 (00:00:08)

03_20_18 combo Final 3.1.55

97:23 Q. Now, that procedure of putting her on a
97:24 heart-lung machine and stopping her heart, that was
97:25 not unique to Ms. Booker or Ms. Booker's condition,
98:1 correct?

98:2 A. No.

98:10 - 98:13

Harvey, Richard 06-20-2017 (00:00:08)

03_20_18 combo Final 3.1.56

98:10 Q. But this was not something that was unique
98:11 just to Ms. Booker, it was something you had done many
98:12 times before and many times since, correct?

98:13 A. Correct.

98:17 - 98:24

Harvey, Richard 06-20-2017 (00:00:22)

03_20_18 combo Final 3.1.57

98:17 Q. You testified that you did not close
98:18 Ms. Booker's pericardium, it heals or repairs itself.
98:19 A. It leaves a defect.
98:20 Q. And by a defect, what do you mean?
98:21 A. If you have to reoperate on somebody, there
98:22 will be -- usually it will have some adhesions and
98:23 there will be a gap, you know, a couple inches wide
98:24 where the pericardium was opened.

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99:5 - 99:19

Harvey, Richard 06-20-2017 (00:00:30)

03_20_18 combo Final 3.1.58

99:5 Q. If I told you that Ms. Booker testified that
 99:6 in October of 2014 she climbed Stone Mountain -- let
 99:7 me back up.
 99:8 Are you familiar with Stone Mountain?
 99:9 A. I am.
 99:10 Q. Have you ever climbed Stone Mountain?
 99:11 A. I have.
 99:12 Q. Okay.
 99:13 A. I was much younger.
 99:14 Q. Okay. If I told you that Ms. Booker
 99:15 testified that in October of 2014 she was able to
 99:16 climb Stone Mountain, would you agree that she had, at
 99:17 least based on that, it appears that she had recovered
 99:18 fairly well from the surgery?
 99:19 A. Yeah.

99:20 - 100:19

Harvey, Richard 06-20-2017 (00:01:01)

03_20_18 combo Final 3.1.59

99:20 Q. What is the normal treatment for a patient
 99:21 who is suffering from pericarditis?
 99:22 A. Nonsteroidals and steroids -- and/or
 99:23 steroids.
 99:24 Q. And you would agree that to treat the
 99:25 pericarditis, if a doctor recommends a nonsteroidal
 100:1 antiinflammatory -- is that right?
 100:2 A. Right. I'm sorry. Yeah.
 100:3 Q. Okay. That's fine.
 100:4 -- that the patient should follow the course
 100:5 and treatment prescribed by the doctor?
 100:6 A. Unless they develop, like, GI symptoms or
 100:7 something like that.
 100:8 Q. Okay. And if a doctor recommends a steroid
 100:9 approach to treat the inflammation, you would again
 100:10 agree that the patient should follow the care and
 100:11 treatment prescribed by the doctor?
 100:12 A. Yeah. Patients often get to feeling better
 100:13 and stop early, yeah. So --
 100:14 Q. And that's a bad thing, right?
 100:15 A. If you don't want it to come back.
 100:16 Q. Okay. So if a patient doesn't want
 100:17 pericarditis to come back, they should complete the

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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	100:18 medication regime prescribed by the doctor, correct?	
	100:19 A. That's correct.	
105:4 - 105:5	Harvey, Richard 06-20-2017 (00:00:03)	03_20_18 combo Final 3_1.61
	105:4 At the time you released Ms. Booker from your	
	105:5 care and treatment in	
105:13 - 105:16	Harvey, Richard 06-20-2017 (00:00:11)	03_20_18 combo Final 3_1.62
	105:13 Q. In September of 2014, she was not reporting	
	105:14 to you and you did not find any objective findings of	
	105:15 any short-term complications, correct, surgical	
	105:16 complications?	
105:24 - 106:3	Harvey, Richard 06-20-2017 (00:00:18)	03_20_18 combo Final 3_1.63
	105:24 A. Yeah, at that time we thought, I guess, the	
	105:25 wound issue and the pleural effusion issue were under	
	106:1 control, and so, you know, we made no notes of any	
	106:2 suggestions of problems or complications at that	
	106:3 time.	
107:1 - 107:4	Harvey, Richard 06-20-2017 (00:00:07)	03_20_18 combo Final 3_1.64
	107:1 Q. And neither Dr. Patel nor Dr. Heller have	
	107:2 consulted with you or referred Ms. Booker back to	
	107:3 you --	
	107:4 A. No.	
109:14 - 109:24	Harvey, Richard 06-20-2017 (00:00:32)	03_20_18 combo Final 3_1.65
	109:14 Q. Assume with me, Doctor, that	
	109:15 subsequent to your discharge of the patient on	
	109:16 September 9, discharge from your care --	
	109:17 A. Office.	
	109:18 Q. -- follow-up office care, that Sherr-Una	
	109:19 Booker has been diagnosed with pericarditis on at	
	109:20 least two separate occasions, assume with me that to	
	109:21 be true. Do you have an opinion whether or not that	
	109:22 is consistent with your knowledge of long-term	
	109:23 complications of the type of procedure which you	
	109:24 performed on Ms. Booker?	
110:1 - 110:12	Harvey, Richard 06-20-2017 (00:00:41)	03_20_18 combo Final 3_1.66
	110:1 A. It is.	
	110:2 Q. Now, you -- just to be clear, when Ms. Helm	
	110:3 was asking you questions about the need for open-heart	
	110:4 surgery and whether it was surgery for the valve or	
	110:5 surgery to retrieve the metal fragment, do you recall	
	110:6 that line of questions?	

03_20_18 combo Final 3_1-Harvey 06-20-17 Booker Depo Desingations Final V3.1

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110:7 A. Yes. Yes.

110:8 Q. If the tricuspid valve had not been

110:9 inadvertently injured during the percutaneous attempt,

110:10 do you have an opinion as to whether or not the

110:11 open-heart surgery still would have been needed and

110:12 still would have been performed by you?

110:15 - 110:17

Harvey, Richard 06-20-2017 (00:00:06)

03_20_18 combo Final 3_1.67

110:15 A. We still would have done the surgery. We

110:16 were worried about a potential perforation, not

110:17 internally, externally.

Plaintiffs Designations = 00:20:32

Defense Designations = 00:09:20

Total Time = 00:29:52

Documents Shown

_1_2361_HARVEY

_1_2364_HARVEY

_3_HARVEY

_4_HARVEY

EXHIBIT H

Designation Run Report

Orms 08-16-16 Booker Depo Designations Final3

Orms, Daniel 08-16-2016

Plaintiffs Designations 00:07:04

DefenseDesignations 00:04:41

Total Time 00:11:45



03_21_18 combo final3-Orms 08-16-16 Booker Depo Designations Final3

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12:19 - 12:20	Orms, Daniel 08-16-2016 (00:00:01) 12:19 I went to work for C.R. Bard 12:20 in 1997.	03_21_18 combo final3.1
15:11 - 15:13	Orms, Daniel 08-16-2016 (00:00:06) 15:11 Q. And you were in the position of 15:12 regional manager from 2008 until? 15:13 A. Until I left at the end of 2012.	03_21_18 combo final3.2
24:17 - 24:24	Orms, Daniel 08-16-2016 (00:00:16) 24:17 Q. Were you provided in your training any 24:18 information to relate to physicians about bench 24:19 testing with regard to the Recovery filter? 24:20 A. No. 24:21 Q. Okay. So you were given no resources to pass 24:22 on to physicians in your region with regard to bench 24:23 testing. 24:24 A. No.	03_21_18 combo final3.3
29:23 - 30:7	Orms, Daniel 08-16-2016 (00:00:28) 29:23 Q. Were you informed by Bard of any other 29:24 deaths associated with the Recovery filter other than 30:1 the one that was reported to you by the sales 30:2 representative in your region? 30:3 A. No, not -- you're saying within that year? 30:4 Q. Sure, let's start with one year. 30:5 A. So, no, no meaning -- and I don't think Bard 30:6 ever -- Bard notified -- no, so Bard didn't make it a 30:7 point of notifying us when an adverse event occurred.	03_21_18 combo final3.61
41:16 - 42:5	Orms, Daniel 08-16-2016 (00:00:29) 41:16 Q. And Bard didn't inform you of any other 41:17 deaths associated with the Recovery filter that year? 41:18 A. I don't believe so. 41:19 Q. What about the year after that? 41:20 A. So I don't think Bard ever notified me and 41:21 said, hey, we had a death. 41:22 Q. Okay. 41:23 A. Any more so than we had any other complication 41:24 for that device or any other device. 42:1 Q. Okay. And therefore you couldn't have shared 42:2 any of that information that you didn't get with any 42:3 of the sales representatives in your territory, 42:4 correct?	03_21_18 combo final3.10

03_21_18 combo final3-Orms 08-16-16 Booker Depo Designations Final3

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96:21 - 97:12

42:5 A. Correct.

Orms, Daniel 08-16-2016 (00:00:32)

03_21_18 combo final3.15

96:21 Q. But did anyone at Bard ever provide

96:22 you like say a report --

96:23 A. Uh-hum.

96:24 Q. -- comparing failure rates between Bard's

97:1 products and competitor products, filters?

97:2 A. I don't believe so, other than what's IFU, was

97:3 it provided in the IFUs for the devices.

97:4 Q. Okay. Which does not provide comparative

97:5 rates between Bard's filters and its competitors.

97:6 A. Correct.

97:7 Q. Okay. And if you were never provided such

97:8 information you couldn't provide it to physicians,

97:9 correct?

97:10 A. Correct.

97:11 Q. Okay. And so you did not, correct?

97:12 A. Correct.

101:24 - 102:9

Orms, Daniel 08-16-2016 (00:00:19)

03_21_18 combo final3.16

101:24 Q. Okay. Were you made aware that the medical

102:1 director of Bard was asking this question of, "The

102:2 G2's a permanent filter; we also have the SNF that has

102:3 virtually no complaints. Why shouldn't doctors be

102:4 using that one rather than the G2?"

102:5 A. No.

102:6 Q. So that information was not provided to you

102:7 while you were on the ground in the territory selling

102:8 or overseeing the sales of G2 filters.

102:9 A. Correct.

105:1 - 105:7

Orms, Daniel 08-16-2016 (00:00:14)

03_21_18 combo final3.17

105:1 Q. And when complaints are reported in

105:2 your region, are they shared amongst the sales

105:3 representatives in your region?

105:4 A. Not as a matter of practice.

105:5 Q. Okay. So that's not a policy at Bard to do

105:6 that?

105:7 A. No.

105:14 - 105:16

Orms, Daniel 08-16-2016 (00:00:03)

03_21_18 combo final3.18

105:14 A. Was it shared?

105:15 Q. Uh-hum.

03_21_18 combo final3-Orms 08-16-16 Booker Depo Designations Final3

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138:18 - 138:23	<p>105:16 A. It would have been word of mouth.</p> <p>Orms, Daniel 08-16-2016 (00:00:09)</p> <p>138:18 Q. But these filters are sold to be</p> <p>138:19 placed in patients, correct?</p> <p>138:20 A. Correct.</p> <p>138:21 Q. Okay. And you're not aware of whether a</p> <p>138:22 patient would like to have the safest filter possible</p> <p>138:23 available implanted in them?</p>	03_21_18 combo final3.19
139:2 - 139:5	<p>Orms, Daniel 08-16-2016 (00:00:09)</p> <p>139:2 A. I guess I would think, yes, they would.</p> <p>139:3 Q. Okay, okay. Is that a big assumption to make</p> <p>139:4 on your part, being someone who's sold filters to be</p> <p>139:5 used in humans for so long?</p>	03_21_18 combo final3.20
139:7 - 139:7	<p>Orms, Daniel 08-16-2016 (00:00:00)</p> <p>139:7 A. No.</p>	03_21_18 combo final3.62
162:3 - 162:5	<p>Orms, Daniel 08-16-2016 (00:00:11)</p> <p>162:3 Meaning, the doctors look to you to advise</p> <p>162:4 them about everything that is available to you about</p> <p>162:5 the product; true?</p>	03_21_18 combo final3.21
162:7 - 162:8	<p>Orms, Daniel 08-16-2016 (00:00:07)</p> <p>162:7 A. Yes.</p> <p>162:8 Q. The good, the bad and the indifferent.</p>	03_21_18 combo final3.22
162:10 - 162:14	<p>Orms, Daniel 08-16-2016 (00:00:15)</p> <p>162:10 A. From my experience, physicians want data that</p> <p>162:11 they can rely on.</p> <p>162:12 Q. Which means open, frank, honest</p> <p>162:13 communications.</p> <p>162:14 A. About data they can rely on, yes.</p>	03_21_18 combo final3.23
167:20 - 167:24	<p>Orms, Daniel 08-16-2016 (00:00:12)</p> <p>167:20 Q. Well, I guess I'm trying to figure out, was</p> <p>167:21 there somebody within Bard that was communicating to</p> <p>167:22 other people in Bard that there were a series of</p> <p>167:23 events going on with say the Recovery. We talked</p> <p>167:24 about the Recovery before.</p>	03_21_18 combo final3.24
168:2 - 168:2	<p>Orms, Daniel 08-16-2016 (00:00:01)</p> <p>168:2 A. To my knowledge, no.</p>	03_21_18 combo final3.25
172:14 - 172:15	<p>Orms, Daniel 08-16-2016 (00:00:04)</p> <p>172:14 Q. somewhere along the line, Bard</p> <p>172:15 learned that tilting in a filter was a bad thing.</p>	03_21_18 combo final3.26
172:17 - 172:21	<p>Orms, Daniel 08-16-2016 (00:00:07)</p>	03_21_18 combo final3.27

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	172:17 A. Yeah, it wasn't optimal. I mean, there's	
	172:18 better -- an improvement to be had.	
	172:19 Q. It was undesirable in a filter, correct?	
	172:20 ***	
	172:21 A. Yes.	
173:14 - 173:19	Orms, Daniel 08-16-2016 (00:00:21)	03_21_18 combo final3.28
	173:14 Q. Well, if there was a group in Bard that was	
	173:15 aware of events with the filter such as the Recovery,	
	173:16 and was aware that the Recovery was tilting and either	
	173:17 causing injuries or causing potential complications to	
	173:18 patients, that's information that you would expect to	
	173:19 be given to you people in sales to use, correct?	
173:21 - 173:21	Orms, Daniel 08-16-2016 (00:00:03)	03_21_18 combo final3.29
	173:21 A. Yeah, it would be good to know.	
174:13 - 174:16	Orms, Daniel 08-16-2016 (00:00:09)	03_21_18 combo final3.30
	174:13 Q. And so you could understand why doctors would	
	174:14 rely on you to -- to, No. 1, assume that you're in the	
	174:15 know and that you would communicate that to the	
	174:16 doctor, correct?	
174:18 - 174:18	Orms, Daniel 08-16-2016 (00:00:01)	03_21_18 combo final3.31
	174:18 A. Yes.	
174:24 - 175:10	Orms, Daniel 08-16-2016 (00:00:32)	03_21_18 combo final3.32
	174:24 A. If the data's meaningful and reliable, yes.	
	175:1 Q. And so that's why it would be reasonable for	
	175:2 you, in the position you were at, and for your	
	175:3 salespeople, to be advised from whoever in Bard was	
	175:4 tracking events and knew what complications or	
	175:5 potential complications those events were causing;	
	175:6 fair?	
	175:7 A. Yes.	
	175:8 Q. And from what you told us today, that really	
	175:9 wasn't something that was going on.	
	175:10 A. No. As a matter of practice, no.	
176:15 - 177:1	Orms, Daniel 08-16-2016 (00:00:29)	03_21_18 combo final3.33
	176:15 Q. Well, how would the conversation go?	
	176:16 A. The conversation would probably go, again, the	
	176:17 physician makes the decision to use any device based on	
	176:18 risk reward, benefit to the patient, and whether it was	
	176:19 Recovery or G2 or G2X or whatever other iterations, the	
	176:20 devices were providing a significant benefit to the	

03_21_18 combo final3-Orms 08-16-16 Booker Depo Designations Final3

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176:21	patient. The doctor has to weigh that versus the risk	
176:22	of the device. And if the risk of the device is within	
176:23	the guidelines of that technology, then that's all that	
176:24	I can do. From a sales perspective, that's all that I	
177:1	can worry about.	
177:9 - 177:11	Orms, Daniel 08-16-2016 (00:00:05)	03_21_18 combo final3.34
177:9	If Bard is aware of problems, with for	
177:10	example the Recovery, I'm saying, that's something you	
177:11	would expect them to advise you; true?	
177:13 - 177:15	Orms, Daniel 08-16-2016 (00:00:06)	03_21_18 combo final3.35
177:13	A. If -- if Bard is aware of problems that are	
177:14	outside of the reporting guidelines, yes, that's what --	
177:15	I would want to know that.	
178:3 - 178:10	Orms, Daniel 08-16-2016 (00:00:12)	03_21_18 combo final3.36
178:3	Q. And you want to be open and you want to be	
178:4	honest.	
178:5	A. And I answered exactly the way I just told you,	
178:6	and I said as far as I know they're well within the SIR	
178:7	guidelines.	
178:8	Q. Okay.	
178:9	A. And the physicians were happy. That was all	
178:10	they wanted to know.	
208:19 - 208:23	Orms, Daniel 08-16-2016 (00:00:07)	03_21_18 combo final3.39
208:19	Q. Does Bard have a	
208:20	responsibility to warn if it becomes aware of a danger	
208:21	associated with its filters? Yes or no.	
208:22	A. Yes.	
208:23	Q. Thank you.	
241:15 - 241:18	Orms, Daniel 08-16-2016 (00:00:05)	03_21_18 combo final3.42
241:15	Q. And resistant to tilt.	
241:16	A. You know, I mean, again, all these adverse	
241:17	events are -- are components of every filter on the	
241:18	market.	
258:17 - 258:19	Orms, Daniel 08-16-2016 (00:00:08)	03_21_18 combo final3.45
258:17	Q. Well, no, follow me. You believed and	
258:18	trusted Bard to thoroughly test the G2 for safety and	
258:19	efficacy, right?	
258:21 - 259:6	Orms, Daniel 08-16-2016 (00:00:43)	03_21_18 combo final3.46
258:21	A. Yes.	
258:22	Q. And it was that expectation that you had that	

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	258:23 gave you the credibility with the doctor, the doctors 258:24 you sold the product to, to give each doctor what you 259:1 believed was accurate information about the G2; fair? 259:2 A. Yes. 259:3 Q. And if, unbeknownst to you, Bard did not 259:4 thoroughly test the G2 for efficacy or safety, that 259:5 would cause you to give inaccurate information to the 259:6 doctor if you believed otherwise; true?	
259:8 - 259:15	Orms, Daniel 08-16-2016 (00:00:18) 259:8 A. If unbeknownst to me they did not do their due 259:9 diligence? 259:10 Q. Yes. 259:11 A. They didn't follow kind of the guidelines and 259:12 the rules of the road? 259:13 Q. Yes. 259:14 A. Yeah, I guess if they're doing something wrong 259:15 and I'm communicating what they're telling me, then yes.	03_21_18 combo final3.47
264:1 - 264:3	Orms, Daniel 08-16-2016 (00:00:06) 264:1 Q. Dan, I have a few more questions for you 264:2 today. The first is, where do you live? 264:3 A. Here in Miami, Florida.	03_21_18 combo final3.48
264:18 - 265:3	Orms, Daniel 08-16-2016 (00:00:29) 264:18 Q. Can you briefly tell us about your 264:19 educational background? I know you mentioned it a 264:20 little bit earlier. 264:21 A. Okay. Yeah, I went to high school here in 264:22 Miami. Graduated from Miami Killian Senior High. Went 264:23 to the University of Florida in Gainesville for four 264:24 years, 1984 through '88, and shortly thereafter got into 265:1 my career as a salesperson. 265:2 Q. You worked for Bard for about 15 years? 265:3 A. Yes, from '97 to 2012.	03_21_18 combo final3.49
265:18 - 266:2	Orms, Daniel 08-16-2016 (00:00:19) 265:18 Q. At any point during your time at Bard did you 265:19 work on the design and development of products? 265:20 A. No. 265:21 Q. Did you have any role in tracking or 265:22 analyzing adverse events? 265:23 A. No. 265:24 Q. Did any of your job responsibilities involve	03_21_18 combo final3.50

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266:1 - 266:15	<p>266:1 determining rates of complications with Bard's 266:2 filters?</p> <p>Orms, Daniel 08-16-2016 (00:00:27)</p> <p>266:5 A. No, no. 266:6 Q. How about competitor filters? 266:7 A. No. 266:8 Q. Was evaluating adverse event reports part of 266:9 your job responsibilities? 266:10 A. No, it was not. 266:11 Q. So all of the questions that you were asked 266:12 today about should Bard have told certain information 266:13 to you, is it part of your job responsibilities when 266:14 you were a district manager and later as a regional 266:15 manager to make that determination?</p>	03_21_18 combo final3.51
266:17 - 266:17	<p>Orms, Daniel 08-16-2016 (00:00:01)</p> <p>266:17 A. No, it was not.</p>	03_21_18 combo final3.52
268:3 - 268:9	<p>Orms, Daniel 08-16-2016 (00:00:13)</p> <p>268:3 Q. During the course of your career you have 268:4 also worked at Ethicon, Steris, and now you're at 268:5 Abbott; is that right? 268:6 A. Yes. 268:7 Q. At any of these companies did the companies 268:8 provide you with individual complaint files for 268:9 products that you were selling?</p>	03_21_18 combo final3.53
268:11 - 268:14	<p>Orms, Daniel 08-16-2016 (00:00:08)</p> <p>268:11 A. No, I was not provided with any of them. 268:12 Q. Did any of these companies provide you with 268:13 MAUDE data to share with physicians? 268:14 A. No.</p>	03_21_18 combo final3.54
282:18 - 283:10	<p>Orms, Daniel 08-16-2016 (00:00:46)</p> <p>282:18 Q. Based on your experience, what are the 282:19 sources from which physicians get their information 282:20 that they use to make decisions about patient 282:21 treatment? 282:22 A. The top two are one is certainly the clinical 282:23 trial data, so level one data from randomized clinical 282:24 trials. Behind that is peer-to-peer, communications, 283:1 conferences, journals, articles that are peer reviewed 283:2 by their -- by their peers. And that's why they have -- 283:3 they carry weight with a physician. So those are really</p>	03_21_18 combo final3.55

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	283:4 the top two areas that they look for I think when making 283:5 a decision. 283:6 Q. Do you believe that physicians rely on 283:7 medical device manufacturers as the primary source of 283:8 information regarding complications associated with 283:9 the medical devices? 283:10 A. No.	
284:16 - 285:5	Orms, Daniel 08-16-2016 (00:00:33) 284:16 Q. We discussed certain adverse events of IVC 284:17 filters during today's deposition, including 284:18 perforation, fracture, migration, tilting, and even 284:19 death. Do you remember those questions during the 284:20 course of today? 284:21 A. Yes, I do. 284:22 Q. Are those adverse events risks that are 284:23 associated with the G2X filter? 284:24 A. Yeah. I mean, those were adverse events -- 285:1 285:2 A. -- that were associated with every -- eery 285:3 filter on the market that's included in every -- every 285:4 one of their IFUs. Physicians are well aware of those 285:5 -- that potential for adverse events.	03_21_18 combo final3.56
285:17 - 285:21	Orms, Daniel 08-16-2016 (00:00:12) 285:17 Q. In your experience in your 15 years at Bard, 285:18 and to your understanding, did physicians know about 285:19 the risks of IVC filters to include perforation, 285:20 fracture, migration, tilting, and irretrievability of 285:21 the filter?	03_21_18 combo final3.57
285:23 - 286:4	Orms, Daniel 08-16-2016 (00:00:16) 285:23 A. Yes. And that's specifically why I kept 285:24 referring to the, in this particular case, the SIR 286:1 guidelines. If the SIR, and this is the Society of 286:2 major body of interventionalists weren't aware of them 286:3 then they wouldn't have guidelines already established 286:4 for adverse events.	03_21_18 combo final3.58
300:4 - 301:5	Orms, Daniel 08-16-2016 (00:00:40) 300:4 Did you ever have possession of any of Bard's 300:5 bench testing? 300:6 A. No. 300:7 Q. Okay. With regard to any of its IVC filters.	03_21_18 combo final3.59

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300:8 A. No.

300:9 Q. Whether retrievable or permanent.

300:10 A. None.

300:11 Q. Okay. And therefore you didn't share any

300:12 results of its bench testing on any of its filters

300:13 with physicians --

300:14 A. No.

300:15 Q. -- that you recall. Including those at

300:16 Cleveland Clinic?

300:17 A. No.

300:18 Q. Were you ever informed that the G2 filter

300:19 failed its migration resistant testing when compared

300:20 to the SNF?

300:21 ***

300:22 A. Was I informed of that?

300:23 Q. Uh-hum.

300:24 A. No.

301:1 Q. You were never informed of that.

301:2 A. I don't believe so.

301:3 Q. Okay. Was that something you would have

301:4 known wanting to sell the product when you're

301:5 marketing both of those products in your territory?

301:7 - 301:10 **Orms, Daniel 08-16-2016 (00:00:12)**

03_21_18 combo final3.60

301:7 A. Is that something I would have wanted to know?

301:8 I guess it would have been beneficial to know.

301:9 Q. Okay. I'm sorry?

301:10 A. It would have been beneficial to know.

Plaintiffs Designations = 00:07:04

DefenseDesignations = 00:04:41

Total Time = 00:11:45

EXHIBIT I

Designation Run Report

Patel 03-22-17 Booker Depo Designations Final3

Patel, Salil 03-22-2017

Plaintiffs Designations 00:22:30

Defense Designations 00:14:52

Plaintiffs Counters 00:00:14

P & D designatiions 00:01:44

Total Time 00:39:20



03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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6:3 - 6:5	Patel, Salil 03-22-2017 (00:00:04)	03_21_18 combo final3.1
6:3	Q. Would you state your full name, please,	
6:4	sir?	
6:5	A. My name is Salil Jayant Patel.	
8:10 - 8:19	Patel, Salil 03-22-2017 (00:00:36)	03_21_18 combo final3.2
8:10	Q. All right. And are you boarded by any	
8:11	particular medical boards?	
8:12	A. I have four board certifications. My main	
8:13	one is cardiology through the ABIM. I have internal	
8:14	medicine board certification also through the ABIM.	
8:15	I'm board certified in nuclear cardiology through the	
8:16	Nuclear Cardiology Society. Then I have one, but it	
8:17	is actually about to expire in cardiovascular CT	
8:18	scans. That was from 2007. This will be the year to	
8:19	renew it if I choose to renew it or not.	
8:23 - 9:1	Patel, Salil 03-22-2017 (00:00:05)	03_21_18 combo final3.3
8:23	Q. All right. And of course, you're licensed	
8:24	to practice medicine in the State of Georgia?	
9:1	A. Yes, sir.	
9:24 - 10:9	Patel, Salil 03-22-2017 (00:00:36)	03_21_18 combo final3.4
9:24	Q. And we are	
10:1	going to provide to you an exhibit which I'm going to	
10:2	mark as Exhibit A, and I'll represent to you this was	
10:3	provided by your group as an authenticated certified	
10:4	copy of your group's medical chart with regard to	
10:5	Ms. Booker. If you could just kind of quickly look	
10:6	at that and state whether or not you're familiar with	
10:7	Ms. Booker's records in this matter?	
10:8	A. Yes, sir. This looks like it's our office	
10:9	chart.	
12:2 - 12:6	Patel, Salil 03-22-2017 (00:00:17)	03_21_18 combo final3.5
12:2	Q. What	
12:3	was the date of the first occasion you had to treat	
12:4	Ms. Booker?	
12:5	A. She came into our office for a	
12:6	consultation, it appears, on January 3rd, 2012.	
12:16 - 12:20	Patel, Salil 03-22-2017 (00:00:17)	03_21_18 combo final3.6
12:16	Q. And if you could tell us what the purpose	
12:17	for the consultation with Ms. Booker was.	
12:18	A. She was sent for preop cardiovascular	

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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13:4 - 13:9	<p>12:19 examination or cardiac clearance, in other terms, 12:20 before planned outpatient hernia surgery.</p> <p>Patel, Salil 03-22-2017 (00:00:13)</p> <p>13:4 Q. And you understood that she was going 13:5 to -- they were contemplating a hernia repair 13:6 procedure, and they wanted your -- your advice with 13:7 regard to whether or not her -- she had any cardiac 13:8 issues which would have made that contraindicated? 13:9 A. Correct.</p>	03_21_18 combo final3.7
13:11 - 13:11	<p>Patel, Salil 03-22-2017 (00:00:01)</p> <p>13:11 THE WITNESS: Yes, sir.</p>	03_21_18 combo final3.8
14:21 - 15:14	<p>Patel, Salil 03-22-2017 (00:01:06)</p> <p>14:21 Q. Well, then, tell us, sir, when the next 14:22 occasion you would have had to -- to be involved in 14:23 Ms. Booker's care or treatment. 14:24 A. Next time I was involved in her care was 15:1 when she was in the hospital at Gwinnett Medical 15:2 Center in July of 2014. 15:3 Q. All right. And what was the occasion or 15:4 the reason for the consult? 15:5 A. So she was -- she was in the hospital 15:6 undergoing procedure by intervention radiology, and 15:7 we were called to come for a cardiology consult. She 15:8 had had an arrhythmia during the procedure. So my 15:9 partner, Dr. Heller, came to see her. She was 15:10 stabilized. Our echocardiogram department did an 15:11 ultrasound, and it was identified that she had 15:12 regurgitation of the tricuspid valve, and so I was 15:13 asked I believe the next day to do a transesophageal 15:14 echocardiogram.</p>	03_21_18 combo final3.10
28:20 - 28:22	<p>Patel, Salil 03-22-2017 (00:00:05)</p> <p>28:20 Q. And this was -- this was also within the 28:21 same procedure, percutaneous approach? 28:22 A. Yes.</p>	03_21_18 combo final3.11
31:1 - 31:2	<p>Patel, Salil 03-22-2017 (00:00:14)</p> <p>31:1 MR. ROLL: I'm going to mark as Exhibit A4 31:2 Dr. Heller's July 23, 2014, consultation note.</p>	03_21_18 combo final3.12
31:10 - 31:21	<p>Patel, Salil 03-22-2017 (00:00:38)</p> <p>31:10 Q. In connection with your consultation and 31:11 your involvement with Ms. Booker's care?</p>	03_21_18 combo final3.13

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31:12 A. Yes.

31:13 Q. What do you understand the reason for

31:14 Dr. Kang to consult with Dr. Heller regarding

31:15 Ms. Booker?

31:16 A. It was really two reasons. She was having

31:17 chest pain at the time of the procedure and also

31:18 primarily having an arrhythmia during the procedure.

31:19 Q. All right. And at that point was there an

31:20 understanding as to what the cause of these

31:21 conditions in the heart was?

31:24 - 32:19

Patel, Salil 03-22-2017 (00:01:06)

03_21_18 combo final3.14

31:24 A. It was felt that they were both related to

32:1 each other. That she was having chest pain because

32:2 her heart was racing so fast, pulse rate at least by

32:3 the notes was as high as 250 beats per minute. The

32:4 episodes were intermittent but went on -- on and off

32:5 for 30 minutes during which she would have the

32:6 sensation of her heart racing and anterior chest

32:7 heaviness.

32:8 Q. Okay. And did you as a consultant form an

32:9 opinion as to whether or not these conditions that

32:10 were being experienced by Ms. Booker were a result of

32:11 the -- the percutaneous attempt to remove this filter

32:12 fragment from her heart?

32:13 A. Well, I think we all felt it was a

32:14 combination of the pre-existing filter being in

32:15 there.

32:16 Q. Yes, sir.

32:17 A. And then the attempt to get it out was

32:18 exciting the heart, and that that was causing her to

32:19 have the arrhythmia.

34:4 - 34:5

Patel, Salil 03-22-2017 (00:00:02)

03_21_18 combo final3.15

34:4 MR. ROLL: Yes, I'm sorry, Exhibit --

34:5 thank you very much -- A5.

34:17 - 35:2

Patel, Salil 03-22-2017 (00:00:31)

03_21_18 combo final3.16

34:17 Q. All right. Do you see on this document

34:18 where after this percutaneous approach that was not

34:19 successful removing the fragment from her heart that

34:20 it's recorded patient's very emotional,

34:21 tearful -- I'm sorry, "Patient very emotional and

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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34:22 tearful at present"?

34:23 A. Yes, I see that note.

34:24 Q. All right. Do you believe that's an

35:1 understanding reaction of Ms. Booker to the events

35:2 that were taking place that day?

35:7 - 35:16

Patel, Salil 03-22-2017 (00:00:28)

03_21_18 combo final3.17

35:7 A. I have seen patients with this sort of

35:8 reaction after these procedures, yes.

35:9 Q. Okay. I mean, based upon your -- your

35:10 understanding and your experience, when a patient is

35:11 being told that even after going through a large

35:12 procedure like this to remove the fragment of the

35:13 heart and being told that this was unsuccessful, the

35:14 fragment is still in there, based upon your

35:15 experiences, is that generally and usually upsetting

35:16 to the patient?

36:6 - 36:7

Patel, Salil 03-22-2017 (00:00:10)

03_21_18 combo final3.18

36:6 MR. ROLL: Okay. I'm looking at here --

36:7 just going to mark this as Exhibit A6.

36:21 - 37:6

Patel, Salil 03-22-2017 (00:00:36)

03_21_18 combo final3.19

36:21 Q. If you could just describe the

36:22 results of your study, the pertinent findings that

36:23 you factored in in rendering consulting advice to the

36:24 physicians taking care of Ms. Booker?

37:1 A. So the main findings of this procedure

37:2 were that the tricuspid valve was disrupted with

37:3 moderate regurgitation and that the filament -- the

37:4 fragments of the filter was seen within the right

37:5 ventricle along the bottom medial part of the

37:6 ventricle, close to the septum.

37:15 - 37:18

Patel, Salil 03-22-2017 (00:00:11)

03_21_18 combo final3.20

37:15 Q. Okay. Based upon the location that is

37:16 documented on this report, do you have an opinion on

37:17 whether or not retrieval of it would have been

37:18 difficult?

37:20 - 38:10

Patel, Salil 03-22-2017 (00:00:41)

03_21_18 combo final3.21

37:20 THE WITNESS: It would be somewhat

37:21 difficult to remove it with a catheter just

37:22 because it was within the muscular fibers of

37:23 that ventricle.

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37:24 Q. (By Mr. Roll) Did you reach a conclusion
38:1 at the time as to what had disrupted the tricuspid
38:2 valve?

38:3 A. Yes.

38:4 Q. And what was your conclusion?

38:5 A. That the catheter attempting to get the
38:6 filament out had quite likely caused some effect on
38:7 the valve.

38:8 Q. All right. And is this a complication of
38:9 the percutaneous procedure approach?

38:10 A. It is.

39:5 - 39:10

Patel, Salil 03-22-2017 (00:00:21)

03_21_18 combo final3.22

39:5 Q. Do you have an opinion to a reasonable
39:6 medical probability as to whether or not the
39:7 complication which arose during the percutaneous
39:8 approach was a complication of a procedure that was
39:9 made necessary by the filter fragment migrating into
39:10 the right ventricle of the heart?

39:12 - 40:9

Patel, Salil 03-22-2017 (00:01:09)

03_21_18 combo final3.23

39:12 THE WITNESS: Yes.

39:13 Q. (By Mr. Roll) Now, based upon -- based
39:14 upon the data that you collected during the TEE, did
39:15 you have conversations with any healthcare providers
39:16 as to the condition of Ms. Booker or what the next
39:17 approach should be?

39:18 A. Yes. A number of us spoke about her case.
39:19 I spoke with Dr. Black. You see Dr. Black's name is
39:20 in this chart. Dr. Black is one of the cardiac
39:21 anesthesiologists. So he was in the case with me
39:22 helping. He was the anesthesiologist, but he also
39:23 does a lot of these tests, these cases. So we talked
39:24 amongst yourselves. I spoke with Dr. Harvey who --
40:1 afterward. I spoke with Dr. Kang afterward to give
40:2 them both the results of the procedure. Both were
40:3 awaiting for the results of the procedure and also to
40:4 find out what my recommendations are or were.

40:5 Q. Okay. And what were your recommendations
40:6 at the time?

40:7 A. That she would need open heart surgery.

40:8 Q. She would need, I'm sorry, what?

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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41:7 - 41:8	40:9 A. Open heart surgery. Patel, Salil 03-22-2017 (00:00:13)	03_21_18 combo final3.24
44:14 - 45:2	41:7 Q. Okay. And let me hand you what I'm going 41:8 to mark as A7. Patel, Salil 03-22-2017 (00:00:42) 44:14 what is listed in boldface type as far as the 44:15 material risks that would have been communicated to 44:16 Ms. Booker in advance of her open heart surgery. 44:17 A. So the form states the following risks: 44:18 "This procedure involves the material risk of 44:19 infection, allergic reaction, severe loss of blood, 44:20 loss or loss of function of any limb or organ, 44:21 paralysis, paraplegia, or quadriplegia, disfiguring 44:22 scar, brain damage, cardiac arrest or death." 44:23 Q. All right. And Ms. Booker would have been 44:24 presented with these risks and the risks explained in 45:1 advance of the open heart procedure? 45:2 A. Yes, sir.	03_21_18 combo final3.25
47:17 - 47:21	Patel, Salil 03-22-2017 (00:00:14) 47:17 Q. Did you continue to 47:18 see Ms. Booker on occasions after she was discharged 47:19 from this Gwinnett Medical Center hospitalization? 47:20 A. I have seen her for follow-up 47:21 appointment -- in follow-up appointments, yeah.	03_21_18 combo final3.26
48:23 - 49:6	Patel, Salil 03-22-2017 (00:00:28) 48:23 Q. And why was it necessary to call a 48:24 cardiothoracic surgeon on Ms. Booker? 49:1 A. Well, there were two reasons to call in a 49:2 cardiothoracic surgeon. One was the tricuspid valve, 49:3 which had been disrupted, but the primary reason was 49:4 that she had this metallic fragment in her right 49:5 ventricle that could not be removed percutaneously 49:6 and had to be removed surgically.	03_21_18 combo final3.27
53:4 - 54:2	Patel, Salil 03-22-2017 (00:01:09) 53:4 Q. (By Mr. Roll) Do you have an opinion 53:5 based upon your role as a cardiac consultant as to 53:6 whether or not it was necessary to remove this metal 53:7 fragment from the right ventricle of Ms. Booker's 53:8 heart? 53:9 A. I believe it had to be removed from her	03_21_18 combo final3.28

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53:10 heart, yes.

53:11 Q. And why is that?

53:12 A. Well, there's -- the risk of leaving a

53:13 foreign object in the right ventricle, I think was

53:14 greater risk leaving it relative to the open heart

53:15 surgery risk.

53:16 Q. And what risk does a patient face that has

53:17 a metal fragment in the right ventricle of his or her

53:18 heart?

53:19 A. Well, the various different risks would be

53:20 perforating the muscle or perforating the heart,

53:21 causing abnormal heart rhythms or arrhythmias, or

53:22 forming blood clots or thrombus on it that could then

53:23 go into the lungs.

53:24 Q. Okay. And would you state whether or not

54:1 those are risks that Ms. Booker would have been

54:2 facing had the metal fragment been left in her heart?

54:4 - 54:4

Patel, Salil 03-22-2017 (00:00:00)

03_21_18 combo final3.29

54:4 THE WITNESS: Yes, they are.

55:16 - 55:18

Patel, Salil 03-22-2017 (00:00:26)

03_21_18 combo final3.30

55:16 MR. ROLL: Let me mark as Exhibit 12 the

55:17 discharge summary for Ms. Booker while -- after

55:18 this procedure.

58:1 - 58:4

Patel, Salil 03-22-2017 (00:00:14)

03_21_18 combo final3.31

58:1 Q. It also records the events that she did

58:2 have some hypertension in the unit and acute blood

58:3 loss, anemia, and was transfused. Do you see this?

58:4 A. Yes.

58:9 - 58:23

Patel, Salil 03-22-2017 (00:00:53)

03_21_18 combo final3.32

58:9 Q. (By Mr. Roll) What are the risks of blood

58:10 transfusion?

58:11 A. The risk of blood transfusion include

58:12 getting the wrong type blood, which would cause a

58:13 massive reaction including breakdown of the blood

58:14 cells, a severe, you know, instability of the vital

58:15 signs. You can have fevers during blood transfusion.

58:16 You can have minor allergic reactions like rash or

58:17 itching. There are the rare risk of infection from a

58:18 transfused blood product, Hepatitis infection or HIV

58:19 infection. Those are the main ones.

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58:20 Q. All right. And Ms. -- would you state
 58:21 whether or not Ms. Booker, in fact, was facing those
 58:22 risks by virtue of receiving the blood transfusion?
 58:23 A. Yes.

65:7 - 66:12

Patel, Salil 03-22-2017 (00:01:25)

03_21_18 combo final3.33

65:7 Q. I believe we were in the process of
 65:8 beginning a discussion with regard to an August 14,
 65:9 2014, visit to Dr. Harvey of which he notified you
 65:10 and your group.

65:11 A. Yes.

65:12 Q. And this is Exhibit A13, and this is page
 65:13 83 of the exhibit. And if you're looking at the top
 65:14 paragraph, what problems postoperatively is
 65:15 Dr. Harvey recording and communicating with you that
 65:16 your patient is experiencing?

REDACTED.1.1

65:17 A. It looks like two main problems. There
 65:18 was an x-ray showing a collection of fluid in the
 65:19 right chest cavity, which is called a right pleural
 65:20 effusion. And the second problem is some pus coming
 65:21 out of the internal jugular site that is on the right
 65:22 side of the neck that was getting better with
 65:23 antibiotic treatment.

clear

REDACTED.1.4

65:24 Q. Okay. So she was having an infection that
 66:1 was revealing itself as pus coming out of a previous
 66:2 drain site?

66:3 A. Yes, sir.

66:4 Q. And in addition to that, she was having
 66:5 fluid around the lung --

66:6 A. Yes.

66:7 Q. -- on the right side?

66:8 A. Yes.

66:9 Q. Were these related to the surgical
 66:10 procedures that she had to have experienced during
 66:11 the previous hospitalization?

66:12 A. Yes.

clear

69:4 - 69:8

Patel, Salil 03-22-2017 (00:00:40)

03_21_18 combo final3.34

69:4 Q. Now, in further review of your
 69:5 records, it appears that Ms. Booker presented to your
 69:6 group vis-a-vis Gwinnett Medical Center on
 69:7 February 23, 2015. I'm going to hand you this

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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69:22 - 70:3	<p>69:8 exhibit which I guess we're up to A14.</p> <p>Patel, Salil 03-22-2017 (00:00:17)</p> <p>69:22 Q. And midway through that records a</p> <p>69:23 "Two-Month history of midsternal chest discomfort,</p> <p>69:24 worse on inspiration and movement with no exertional</p> <p>70:1 component, no shortness of breath, no diaphoresis."</p> <p>70:2 Did I read that correctly?</p> <p>70:3 A. Yes.</p>	03_21_18 combo final3.35
70:19 - 72:3	<p>Patel, Salil 03-22-2017 (00:01:27)</p> <p>70:19 Q. she received a CT scan, and that was</p> <p>70:20 the next, Exhibit A15?</p> <p>70:21 A. Yes, sir.</p> <p>70:22 Q. All right. And with regard to the CT</p> <p>70:23 scan, this indicates that she had old epicardial</p> <p>70:24 pacer leads which remain in place. Do you see this</p> <p>71:1 in the first paragraph?</p> <p>71:2 A. Yes, sir.</p> <p>71:3 Q. What are pacer leads?</p> <p>71:4 A. Those are wires that we will use to pace</p> <p>71:5 the heart. They can be part of a permanent pacemaker</p> <p>71:6 device. Or in her case, it was part of a temporary</p> <p>71:7 pacemaker device, which is a standard device that</p> <p>71:8 patients going through open heart surgery will get.</p> <p>71:9 I mean, we will give them a temporary pacemaker as</p> <p>71:10 part of the support to get them through surgery.</p> <p>71:11 Q. So are these pieces of metal?</p> <p>71:12 A. These are wires.</p> <p>71:13 Q. Wires.</p> <p>71:14 A. Metal wires.</p> <p>71:15 Q. Okay. And these metal wires as recorded</p> <p>71:16 by this CT scan that was performed in 2015 were</p> <p>71:17 still -- still in the heart?</p> <p>71:18 A. Still in the chest on the -- they touch</p> <p>71:19 the outside of the heart, but they're really</p> <p>71:20 primarily within the chest cavity.</p> <p>71:21 Q. Right. But the purpose is for the wires</p> <p>71:22 to touch the chest for a previous use of a temporary</p> <p>71:23 pacemaker during the open heart surgery?</p> <p>71:24 A. Yes.</p> <p>72:1 Q. These wires are still in the body of</p>	03_21_18 combo final3.36

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72:2 Ms. Booker?

72:3 A. Yes.

72:15 - 72:18

Patel, Salil 03-22-2017 (00:00:11)

03_21_18 combo final3.37

72:15 you saw Ms. Booker then on August 6th, 2016,

72:16 correct?

72:17 A. '16, yes, sir.

72:18 MR. ROLL: I think we're up to A16.

73:7 - 74:22

Patel, Salil 03-22-2017 (00:02:20)

03_21_18 combo final3.38

73:7 Q. And what was the reason -- what was

73:8 her -- what was her complaint and what was the reason

73:9 she came?

73:10 A. Because of chest pain.

73:11 Q. All right. And at that point did you work

73:12 her up for an explanation for her chest pain?

73:13 A. So I saw her in the office, did a history,

73:14 took a history. I did a physical examination. I

73:15 ordered an echocardiogram. For that particular day,

73:16 my impression was that this was pain related to a

73:17 pericarditis.

73:18 Q. Okay.

73:19 A. And I put her on medicine.

73:20 Q. So could you explain to us what

73:21 pericarditis is?

73:22 A. Pericarditis means inflammation of the

73:23 lining around the heart, the pericardium.

73:24 Q. The pericardium, is it a membrane that

74:1 surrounds the heart?

74:2 A. Yes.

74:3 Q. And is this related to her open heart

74:4 surgery that she had previously undergone in 2014?

74:5 A. My impression was this was a result of her

74:6 previous open heart surgery.

74:7 Q. Is pericarditis a common or an uncommon

74:8 sequelae of patients undergoing open heart surgery?

74:9 A. It's a common occurrence.

74:10 Q. And does this inflammation of the membrane

74:11 surrounding a patient's heart does that cause pain?

74:12 A. Yes.

74:13 Q. How does it cause pain?

74:14 A. Well, it's those inflamed surfaces rubbing

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74:15 against each other that -- it hurts those surfaces.

74:16 It hurts the inside of their chest cavity.

74:17 Q. Okay. And based upon your examination,

74:18 the history taking and any tests that you ran, would

74:19 you state whether or not it was your opinion that

74:20 she, in fact, was suffering from pericarditis?

74:21 A. It was my opinion that, yes, this was

74:22 pericarditis.

74:23 - 75:10

Patel, Salil 03-22-2017 (00:00:30)

03_21_18 combo final3.39

74:23 Q. On the last page of

74:24 your report for this visit, you listed signs and

75:1 symptoms consistent with acute recurrent

75:2 pericarditis?

75:3 A. Yes.

75:4 Q. With history of open heart surgery

75:5 since -- surgery, previous tricuspid valve repair?

75:6 A. Yes.

75:7 Q. All right. Now, what do you mean by

75:8 recurrent pericarditis?

75:9 A. She said that she had the same symptoms

75:10 right after the open heart surgery.

75:13 - 76:6

Patel, Salil 03-22-2017 (00:00:45)

03_21_18 combo final3.40

75:13 Q. Okay. Now, this is not in your record,

75:14 but assume with me that she was admitted on September

75:15 30, 2015, to Piedmont Healthcare Hospital and

75:16 discharged on October 2nd, 2015, with an admission

75:17 and discharge diagnosis of pericarditis.

75:18 A. Of which year? 2016 or --

75:19 Q. I'm sorry, 2015. This is September 30 of

75:20 2015.

75:21 A. 2015, yes, yes.

75:22 Q. So this would have been September of 2015,

75:23 and she saw you almost a year later in August of

75:24 2016.

76:1 A. Yes.

76:2 Q. Both with a diagnosis of pericarditis.

76:3 A. Yes.

76:4 Q. Is that consistent with your labeling this

76:5 is recurrent pericarditis in your notes?

76:6 A. Yes.

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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76:8 - 76:12	Patel, Salil 03-22-2017 (00:00:17) 76:8 Q. (By Mr. Roll) Is this something that you 76:9 as a cardiologist are surprised to see in a patient 76:10 that underwent the type of open heart surgery that 76:11 Ms. Booker underwent in 2014? 76:12 A. No.	03_21_18 combo final3.41
76:20 - 77:4	Patel, Salil 03-22-2017 (00:00:34) 76:20 Q. Do you have an opinion as to whether or 76:21 not Ms. Booker's percutaneous procedure which she 76:22 underwent on July 23, 2014, was made necessary by 76:23 the -- by the fragments and migration of Ms. Booker's 76:24 filter -- 77:1 77:2 Q. (By Mr. Roll) -- parts? 77:3 A. Yes. I believe the percutaneous procedure 77:4 was indicated.	03_21_18 combo final3.43
77:9 - 77:12	Patel, Salil 03-22-2017 (00:00:13) 77:9 Q. Do you have an opinion as to whether or 77:10 not the open heart surgery which Ms. Booker underwent 77:11 on July 28, 2014, was made necessary by the 77:12 fragmentation of her filter?	03_21_18 combo final3.44
77:14 - 77:17	Patel, Salil 03-22-2017 (00:00:08) 77:14 THE WITNESS: Yes. 77:15 Q. (By Mr. Roll) And what is that opinion? 77:16 A. That, yes, it was made necessary by the 77:17 fractured filament.	03_21_18 combo final3.45
77:21 - 77:24	Patel, Salil 03-22-2017 (00:00:19) 77:21 Do you have an opinion as to whether or 77:22 not the recurrent pericarditis that Ms. Booker 77:23 reported to you in August of 2016 is a result of her 77:24 open heart surgery of July 28, 2014?	03_21_18 combo final3.46
78:2 - 78:4	Patel, Salil 03-22-2017 (00:00:07) 78:2 THE WITNESS: Yes. My opinion is that, 78:3 yes, the pericarditis is a result of the open 78:4 heart surgery.	03_21_18 combo final3.47
78:13 - 78:18	Patel, Salil 03-22-2017 (00:00:18) 78:13 sitting here today, so to speak, with Ms. Booker's 78:14 history of having gone through the percutaneous 78:15 procedure, then the open heart procedure, knowing 78:16 what you know about Ms. Booker, generally, what risks	03_21_18 combo final3.48

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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78:20 - 79:2	<p>78:17 does she have that a patient of the normal patient 78:18 population group would not be facing? Patel, Salil 03-22-2017 (00:00:25) 78:20 THE WITNESS: Ms. Booker's ongoing risks 78:21 because of her previous open heart surgery 78:22 includes recurrent pericarditis, risk for 78:23 arrhythmia because of previous open heart 78:24 surgery, and also risk of the surgically 79:1 repaired valve further deteriorating or 79:2 not -- not functioning normally down the road.</p>	03_21_18 combo final3.49
80:7 - 80:9	<p>Patel, Salil 03-22-2017 (00:00:04) 80:7 Did you meet with any of Ms. Booker's 80:8 lawyers prior to today? 80:9 A. Yes.</p>	03_21_18 combo final3.50
80:23 - 81:1	<p>Patel, Salil 03-22-2017 (00:00:07) 80:23 Q. And in that meeting, did they show you any 80:24 documents or did you discuss any documents? 81:1 A. We looked at the same records, yes.</p>	03_21_18 combo final3.51
81:23 - 82:1	<p>Patel, Salil 03-22-2017 (00:00:07) 81:23 Q. And have you been asked to be paid for 81:24 your deposition today? 82:1 A. My company is being paid today.</p>	03_21_18 combo final3.52
83:12 - 83:18	<p>Patel, Salil 03-22-2017 (00:00:12) 83:12 Q. Did you tell them last week the opinions 83:13 that you've offered today in your deposition? 83:14 A. Some of the things that I've said today 83:15 they heard last week. 83:16 Q. They asked you those same questions last 83:17 week? 83:18 A. Yes.</p>	03_21_18 combo final3.53
84:4 - 84:6	<p>Patel, Salil 03-22-2017 (00:00:04) 84:4 How long did you meet with 84:5 Mr. Roll and Ms. Lourie last week? 84:6 A. About 90 minutes.</p>	03_21_18 combo final3.54
85:14 - 85:22	<p>Patel, Salil 03-22-2017 (00:00:21) 85:14 Q. Okay. Are you aware of the known risks 85:15 and complications of IVC filters? 85:16 A. In a general sense, yes. 85:17 Q. Okay. Are you aware that fracture is a 85:18 known complication of IVC filters?</p>	03_21_18 combo final3.55

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85:19 A. In a -- yes, ma'am.

85:20 Q. Okay. As is thrombosis and embolization,

85:21 correct?

85:22 A. Yes, ma'am.

86:11 - 86:13

Patel, Salil 03-22-2017 (00:00:07)

03_21_18 combo final3.56

86:11 start with your first treatment

86:12 of Ms. Booker on January 3, 2012.

86:13 A. Yes.

86:17 - 87:5

Patel, Salil 03-22-2017 (00:00:30)

03_21_18 combo final3.57

86:17 Q. Okay. At the time she presented to you,

86:18 she provided you with some background and history

86:19 correct?

86:20 A. Correct.

86:21 Q. And she told you that she had a history of

86:22 myocardial infarction; is that right?

86:23 A. Correct.

86:24 Q. That's a heart attack, right?

87:1 A. Yes.

87:2 Q. Okay. And she told you that she had had a

87:3 heart attack as a result of a reaction to general

87:4 anesthesia; is that right?

87:5 A. Yes.

87:20 - 88:4

Patel, Salil 03-22-2017 (00:00:23)

03_21_18 combo final3.93

87:20 Q. Number one, it says, mitral valve

87:21 prolapse. What is that?

87:22 A. That is an abnormality of the mitral valve

87:23 where it has a backward movement as it's closing. It

87:24 doesn't stay tight. So it kind of slipped backward,

88:1 which is prolapse. So it moved further back in the

88:2 left atrium.

88:3 Q. Okay. That's in her heart, right?

88:4 A. Yes, ma'am.

90:13 - 91:4

Patel, Salil 03-22-2017 (00:00:38)

03_21_18 combo final3.58

90:13 Q. the one thing that is not in your

90:14 record from when you treated Ms. Booker on January 3,

90:15 2012, is the fact that she had an IVC filter

90:16 implanted, is it?

90:17 A. Correct.

90:18 Q. She did not tell you that, did she?

90:19 A. I don't think she did. That's why I said

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90:20 before I wasn't -- I don't recall being aware of it

90:21 at the time I saw her.

90:22 Q. Well, if you look at the three pages of

90:23 Exhibit A1, which is your complete note relating to

90:24 your treatment of her on that day --

91:1 A. Yes.

91:2 Q. -- is there any attention in there of an

91:3 IVC filter?

91:4 A. It's not.

91:9 - 91:11 **Patel, Salil 03-22-2017 (00:00:05)**

03_21_18 combo final3.59

91:9 Q. Well, did you know she had an IVC

91:10 filter?

91:11 A. I just don't recall at the time.

91:12 - 91:21 **Patel, Salil 03-22-2017 (00:00:12)**

03_21_18 combo final3.60

91:12 Q. Well, you certainly didn't record it, did

91:13 you?

91:14 A. I didn't record it in my note.

91:15 Q. And isn't that something that -- through

91:16 the regular course of your treatment of a patient you

91:17 would record if a patient told you they had an IVC

91:18 filter?

91:19 A. Yes, I would.

91:20 Q. And it's not here?

91:21 A. Correct.

93:10 - 93:20 **Patel, Salil 03-22-2017 (00:00:29)**

03_21_18 combo final3.61

93:10 Q. prior to Ms. Booker, you have not been

93:11 involved in treating a patient who had a

93:12 surgical -- a non-percutaneous removal of the filter

93:13 or any part of the filter; is that right?

93:14 A. Correct.

93:15 Q. So -- and as far as you know, no one else

93:16 in your group -- at least no one else in your group

93:17 informed you that they have ever treated anyone who

93:18 had had a -- required a surgical removal of the

93:19 filter or part of the filter; is that right?

93:20 A. Right.

94:6 - 94:18 **Patel, Salil 03-22-2017 (00:00:38)**

03_21_18 combo final3.62

94:6 Q. Let me ask it this way. She actually

94:7 presented with kidney stones, didn't she?

94:8 A. She was being evaluated for kidney stones

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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94:9 and had a CT scan that discovered the fractured
 94:10 filter; and I believe that study, that CAT scan study
 94:11 also found the fragment in the right ventricle.
 94:12 Q. But that was an incidental finding to the
 94:13 CT scan relating to the kidney stones, correct?
 94:14 A. That is my understanding, yes.
 94:15 Q. And as far as you know, she didn't present
 94:16 with any symptoms related -- that anyone attributed
 94:17 to the filter or the fragment, did she?
 94:18 A. That's my -- yes, correct.

94:21 - 95:2

Patel, Salil 03-22-2017 (00:00:09)

03_21_18 combo final3.63

94:21 Q. She did not present with any symptoms that
 94:22 were attributed to the filter or the fragment,
 94:23 correct?
 94:24 A. In the -- in the heart fragment?
 95:1 Q. Correct.
 95:2 A. Correct.

96:22 - 97:3

Patel, Salil 03-22-2017 (00:00:11)

03_21_18 combo final3.64

96:22 Q. There's no documentation of any consult or
 96:23 recommendation by any cardiologist or
 96:24 cardiac -- cardiothoracic surgeon --
 97:1 ***

97:2 Q. (By Ms. Helm) -- prior to the
 97:3 percutaneous retrieval, correct?

97:6 - 97:7

Patel, Salil 03-22-2017 (00:00:03)

03_21_18 combo final3.65

97:6 THE WITNESS: I don't think there's any
 97:7 documents of that nature.

99:1 - 99:10

Patel, Salil 03-22-2017 (00:00:37)

03_21_18 combo final3.66

99:1 Q. At this point in time, looking at
 99:2 Dr. Kang's procedure radiology report, do you know
 99:3 where the strut was in the right ventricle?
 99:4 A. Not based on this report, no.
 99:5 Q. Okay. So you don't know if it was
 99:6 endothelialized or embedded in the exterior tissue of
 99:7 the right ventricle?
 99:8 A. Based on this report, no.
 99:9 Q. Did you subsequently learn where the strut
 99:10 was in the right ventricle?

99:16 - 99:18

Patel, Salil 03-22-2017 (00:00:08)

03_21_18 combo final3.67

99:16 THE WITNESS: Based on my review of the CT

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99:22 - 100:6	<p>99:17 and of the TEE, there was two -- the two ends 99:18 were embedded and covered with endothelium.</p> <p>Patel, Salil 03-22-2017 (00:00:10)</p> <p>99:22 but the two ends were endothelialized into the 99:23 muscle tissue? 99:24 A. Were embedded in the muscle. 100:1 Q. Embedded, correct? 100:2 A. Yes. 100:3 Q. In other words, muscle tissue had -- was 100:4 surrounding the -- 100:5 A. Yes. 100:6 Q. -- ends of the strut?</p>	03_21_18 combo final3.68
104:24 - 105:16	<p>Patel, Salil 03-22-2017 (00:00:50)</p> <p>104:24 Q. And there's no question that that tear 105:1 occurred during the attempts by Dr. Kang going 105:2 through the tricuspid valve to try to retrieve the 105:3 strut? 105:4 A. Correct. 105:5 Q. And in the TEE, you could also see the 105:6 fragment that was still in the -- in the strut, and 105:7 you could see that it was within the muscular fibers 105:8 near the tricuspid valve, correct? 105:9 A. I could see it's -- I could see its 105:10 location. I couldn't see those muscular fibers on 105:11 the TEE. I think that was better described or better 105:12 seen on the CAT scan. 105:13 Q. And on the CAT scan it showed that it was 105:14 in the muscular fibers with the ends embedded into 105:15 those fibers, correct? 105:16 A. Correct.</p>	03_21_18 combo final3.70
106:2 - 106:22	<p>Patel, Salil 03-22-2017 (00:00:48)</p> <p>106:2 Let's start with the premise of this was the very 106:3 first time you had ever seen a fractured strut of an 106:4 IVC filter in the heart, correct? 106:5 A. Yes, ma'am. 106:6 Q. Okay. Based on that premise, you don't 106:7 know -- you had no experience as to whether a strut 106:8 such as Ms. Booker's which was embedded into the 106:9 muscle would cause any symptoms or not, correct? 106:10 A. In -- correct.</p>	03_21_18 combo final3.71

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	106:11 Q. Okay. Likewise, you don't have any	
	106:12 experience to know whether that strut, which you said	
	106:13 the ends were embedded in the muscle, whether that	
	106:14 strut was going to move again?	
	106:15 A. Correct.	
	106:16 Q. And you also don't know how long it had	
	106:17 been there?	
	106:18 A. Correct.	
	106:19 Q. Okay. And so it is fair to say you don't	
	106:20 know if -- whether it could have stayed and remained	
	106:21 asymptomatic, correct?	
	106:22 A. Correct.	
112:11 - 112:20	Patel, Salil 03-22-2017 (00:00:28)	03_21_18 combo final3.72
	112:11 Q. She did not have an open chest procedure?	
	112:12 A. She had a -- to be very precise, she had a	
	112:13 minithor -- thoracotomy approach for open heart	
	112:14 surgery rather than a traditional median sternotomy	
	112:15 approach for open heart surgery.	
	112:16 Q. And while both are invasive, this one is	
	112:17 less invasive, correct?	
	112:18 A. It is felt to be a -- less invasive and a	
	112:19 little bit easier to recover from compared to a	
	112:20 sternotomy.	
115:18 - 116:9	Patel, Salil 03-22-2017 (00:00:35)	03_21_18 combo final3.73
	115:18 Q. Okay. And then it says in discharge	
	115:19 instructions, "The patient was to follow-up with	
	115:20 Dr. Harvey in two weeks at which time we will get a	
	115:21 repeat x-ray and she is to follow-up with her	
	115:22 cardiologist in two to three weeks." Is that what it	
	115:23 says?	
	115:24 A. That's what it says, yes.	
	116:1 Q. Okay. And at that time were you -- did	
	116:2 you consider yourself to be her cardiologist?	
	116:3 A. Well, I had seen her in the office. So	
	116:4 that would have been the natural person to follow-up	
	116:5 with her.	
	116:6 Q. Okay. But other than Dr. Harvey, she	
	116:7 didn't follow-up with anyone in your office for	
	116:8 almost two years, correct?	
	116:9 A. Correct.	

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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118:4 - 118:6	Patel, Salil 03-22-2017 (00:00:13) 118:4 Q. Then you, your office and Gwinnett Medical 118:5 Center don't see Ms. Booker again until February of 118:6 2015, correct?	03_21_18 combo final3.74
118:13 - 118:14	Patel, Salil 03-22-2017 (00:00:04) 118:13 A. From my practice, there's a six-month gap, 118:14 yes.	03_21_18 combo final3.75
118:15 - 118:18	Patel, Salil 03-22-2017 (00:00:07) 118:15 Q. And she did not follow-up with you 118:16 as recommended by Dr. Harvey? 118:17 A. Correct.	03_21_18 combo final3.76
118:18 - 118:20	118:18 Q. And she presented to the ER Patel, Salil 03-22-2017 (00:00:13) 118:18 Q. And she presented to the ER -- and I'm on 118:19 A14. She presented to the ER in February of 2014, 118:20 and the CT scan was normal that they performed on	03_21_18 combo final3.77
119:1 - 119:14	Patel, Salil 03-22-2017 (00:00:54) 119:1 A. So A15, CT scan, February 22, 2015. No 119:2 sign of pulmonary embolism. No acute cardiopulmonary 119:3 disease process. Yes, ma'am. 119:4 Q. Okay. There's nothing in the report that 119:5 was done by a PA in your group, Geen James, per 119:6 Dr. Sharma or in the CT scan that indicates that 119:7 Ms. Booker's subjective complaints of chest pain are 119:8 related to the prior surgery, is there? 119:9 A. No, there's not. 119:10 Q. And likewise, there's no indication in 119:11 this report or in the CT scan that her chest pain is 119:12 in any way related to the strut that's still in her 119:13 IVC, is there? 119:14 A. Correct.	03_21_18 combo final3.78
120:23 - 121:4	Patel, Salil 03-22-2017 (00:00:21) 120:23 Q. Okay. The last time you saw Ms. Booker 120:24 was on August 6 -- August 8th, 2016; is that right? 121:1 A. August 8, 2016, yes. 121:2 Q. And she complained of dizziness and 121:3 unspecified chest pain; is that right? 121:4 A. Correct.	03_21_18 combo final3.79
121:21 - 122:1	Patel, Salil 03-22-2017 (00:00:13) 121:21 Q. And you were going to check her ANA levels	03_21_18 combo final3.80

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121:22 to rule out some sort of rheumatological or 121:23 autoimmune -- 121:24 A. To rule out lupus is the thing I was 122:1 looking for.		
123:16 - 123:24	Patel, Salil 03-22-2017 (00:00:26) 123:16 Q. In this case, your impression of 123:17 pericarditis was based on her subjective symptoms and 123:18 her description to you, correct? 123:19 A. Yes, ma'am. 123:20 Q. And at least with the objective testing 123:21 that you did, it did not support -- there was no 123:22 findings in that objective testing to support 123:23 pericarditis, correct? I understand it didn't rule 123:24 it out. But it did not support it, correct?	03_21_18 combo final3.81
124:1 - 124:13	Patel, Salil 03-22-2017 (00:00:31) 124:1 A. yes, you're correct. If I may 124:2 elaborate, or I'll just stay quiet if you want me to 124:3 stay quiet. 124:4 MR. ROLL: Elaborate. 124:5 THE WITNESS: The tests were not to make 124:6 the diagnosis of pericarditis. The tests were 124:7 to look for other issues that can relate to 124:8 pericarditis. Does someone have lupus? Do they 124:9 have an effusion with their pericarditis? Is 124:10 there something happening in the valve? So the 124:11 point of the test was not to make the diagnosis 124:12 of pericarditis. That was already made based on 124:13 my clinical judgment.	03_21_18 combo final3.82
124:20 - 125:1	Patel, Salil 03-22-2017 (00:00:18) 124:20 Q. And I believe you testified earlier that 124:21 while not impossible, it is not common for someone to 124:22 have pericarditis as a -- two years after heart 124:23 surgery? 124:24 A. It is one of the well-known but not common 125:1 sequelae of open heart surgery.	03_21_18 combo final3.83
125:17 - 126:3	Patel, Salil 03-22-2017 (00:00:26) 125:17 Q. How did you treat the diagnosis of 125:18 pericarditis in August of 2016? 125:19 A. We tried her on a medicine called 125:20 Colchicine which is commonly used for gout, but	03_21_18 combo final3.84

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	<p>125:21 actually is one of the more successful medicines to</p> <p>125:22 treat pericarditis. She did not tolerate it. I</p> <p>125:23 don't remember exactly why. So we ended up putting</p> <p>125:24 her on steroids, Prednisone, and referred her to see</p> <p>126:1 a rheumatologist.</p> <p>126:2 Q. And where is that in your notes in your</p> <p>126:3 record?</p>	
126:16 - 127:8	<p>Patel, Salil 03-22-2017 (00:00:43)</p> <p>126:16 , August</p> <p>126:17 23rd, message to myself -- from my nurse to me,</p> <p>126:18 "Colchicine causing diarrhea and vomiting." Well,</p> <p>126:19 that's a known side effect. She stopped the</p> <p>126:20 Colchicine and is calling for further recommendation.</p> <p>126:21 My message back to the nurse was, you know, Our only</p> <p>126:22 other option is steroids in a slow taper six weeks,</p> <p>126:23 but has to see Dr. Glen Paris -- that's one of the</p> <p>126:24 local rheumatologists -- for further management of</p> <p>127:1 this.</p> <p>127:2 Q. Do you know if Ms. Booker filled the</p> <p>127:3 prescription for steroids?</p> <p>127:4 A. I don't know.</p> <p>127:5 Q. Do you know if she ever went to Dr. Paris?</p> <p>127:6 A. I don't know.</p> <p>127:7 Q. But she never came back to you --</p> <p>127:8 A. Correct.</p>	03_21_18 combo final3.85
130:2 - 130:6	<p>Patel, Salil 03-22-2017 (00:00:15)</p> <p>130:2 Would you state whether or not one of your</p> <p>130:3 diagnoses with regard to Ms. Booker on August 8,</p> <p>130:4 2016, is, in fact, pericarditis?</p> <p>130:5 A. Yes. That's still my diagnosis for that</p> <p>130:6 date.</p>	03_21_18 combo final3.86
130:11 - 130:14	<p>Patel, Salil 03-22-2017 (00:00:08)</p> <p>130:11 Q. And do you believe to a reasonable medical</p> <p>130:12 probability that she, in fact, was experiencing the</p> <p>130:13 effects of pericarditis on that day?</p> <p>130:14 A. Yes.</p>	03_21_18 combo final3.87
131:15 - 132:7	<p>Patel, Salil 03-22-2017 (00:00:52)</p> <p>131:15 Q. (By Mr. Roll) And did you have an opinion</p> <p>131:16 as to whether or not it was a medically prudent</p> <p>131:17 decision to take the strut out of the right ventricle</p>	03_21_18 combo final3.88

03_21_18 combo final3-Patel 03-22-17 Booker Depo Designations Final3

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	131:18 rather than leaving it in?	
	131:19 A. I do think that was a prudent step.	
	131:20 Q. And why is that?	
	131:21 A. Because of the uncertainty. I have had	
	131:22 other people with embolizations to the heart, not an	
	131:23 IVC filter, but catheters that have broken off and	
	131:24 gone to the heart.	
	132:1 Q. Okay.	
	132:2 A. And in those -- so in approaching these	
	132:3 cases, when we have a -- you know, an available good	
	132:4 cardiac surgeon that we can use that I think	
	132:5 the -- the risks of the surgery are smaller than the	
	132:6 risk of leaving this foreign object in their -- in	
	132:7 their heart.	
135:21 - 135:23	Patel, Salil 03-22-2017 (00:00:06)	03_21_18 combo final3.89
	135:21 Q. (By Mr. Roll) In your contact with	
	135:22 Ms. Booker, did she strike you as someone who would	
	135:23 just make symptoms up?	
136:4 - 136:5	Patel, Salil 03-22-2017 (00:00:03)	03_21_18 combo final3.90
	136:4 A. I believe that she was really having the	
	136:5 symptoms that she was telling me.	
136:10 - 136:24	Patel, Salil 03-22-2017 (00:00:36)	03_21_18 combo final3.91
	136:10 If you would look at	
	136:11 Exhibit A16 one more time.	
	136:12 A. Yes, ma'am.	
	136:13 Q. On the last page under "Today's orders,"	
	136:14 order number two was "Return visit in three weeks,"	
	136:15 is that right?	
	136:16 A. Yes, ma'am.	
	136:17 Q. And she did not return to your office, did	
	136:18 she?	
	136:19 A. Correct.	
	136:20 Q. And then between the surgery in 2014 and	
	136:21 when you saw Ms. Booker in August of 2016, are you	
	136:22 aware that she was involved in May of 2015 in a motor	
	136:23 vehicle accident?	
	136:24 A. No, ma'am.	
137:7 - 137:20	Patel, Salil 03-22-2017 (00:00:29)	03_21_18 combo final3.92
	137:7 Q. Would it	
	137:8 have been important for you to know in August of 2016	

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137:9 that Ms. Booker had been involved in an automobile
 137:10 accident and diagnosed with a chest wall contusion?
 137:11 A. It would have been a minor factor, yes.
 137:12 Q. But a factor?
 137:13 A. Yes.
 137:14 Q. And you were not aware of that until I
 137:15 told you?
 137:16 A. Correct.
 137:17 Q. Okay. So you weren't aware that she was
 137:18 treated in the emergency room at Gwinnett Medical
 137:19 Center on August 5 -- 22, 2015?
 137:20 A. Right.

Plaintiffs Designations = 00:22:30

Defense Designations = 00:14:52

Plaintiffs Counters = 00:00:14

P & D designatiions = 00:01:44

Total Time = 00:39:20

Documents Shown

REDACTED

EXHIBIT J

Designation Run Report

Schultz 01-30-14 Booker Depo Designations Final 4

Shultz, Gin 01-30-2014

Plaintiffs Designations 00:23:22

Defense Designations 00:09:30

Total Time 00:32:52



03_21_18 Combo Final4-Schultz 01-30-14 Booker Depo Designations Final 4

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13:17 - 13:18	Shultz, Gin 01-30-2014 (00:00:01) 13:17 Q. Good morning, Ms. Schulz. 13:18 A. Good morning.	03_21_18 Combo Final4.1
26:11 - 26:13	Shultz, Gin 01-30-2014 (00:00:09) 26:11 Q. And when did you first start 26:12 working at Bard? 26:13 A. 2005. October 3rd, 2005.	03_21_18 Combo Final4.2
49:8 - 49:11	Shultz, Gin 01-30-2014 (00:00:09) 49:8 Okay. What was your title 49:9 when you were hired at Bard? 49:10 A. I believe it was VP of 49:11 quality assurance.	03_21_18 Combo Final4.3
50:17 - 50:24	Shultz, Gin 01-30-2014 (00:00:24) 50:17 I also had responsibility of 50:18 monitoring the performance of the overall 50:19 system. I reported -- or had the process 50:20 of reporting out to our executive team at 50:21 BPV as well as to my supervisor who was 50:22 at corporate. 50:23 Q. Who was your supervisor? 50:24 A. Chris Ganser.	03_21_18 Combo Final4.4
54:19 - 54:21	Shultz, Gin 01-30-2014 (00:00:02) 54:19 Q. Okay. And you're currently 54:20 still at Bard, correct? 54:21 A. Yes.	03_21_18 Combo Final4.5
57:24 - 58:11	Shultz, Gin 01-30-2014 (00:00:22) 57:24 Q. Okay. I'm just asking your 58:1 opinion as a quality person, and you've 58:2 been in the field for a long time. If 58:3 you have a device on the market where its 58:4 risks exceed its benefits, in the 58:5 company's opinion, should you pull it 58:6 from the market? 58:7 A. You would -- your process 58:8 and procedures would pull it -- pull it 58:9 from the market. If -- if the risks 58:10 exceeded the benefit, you would do it 58:11 much quicker.	03_21_18 Combo Final4.6
68:24 - 69:2	Shultz, Gin 01-30-2014 (00:00:07) 68:24 does a customer have the right to be made	03_21_18 Combo Final4.7

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69:9 - 69:23

69:1 aware of the -- all known risks that the
69:2 company is aware of regarding the device?

Shultz, Gin 01-30-2014 (00:00:43)

03_21_18 Combo Final4.8

69:9 A. Through our labeling, we
69:10 will put -- we actually go through and we
69:11 evaluate all of the risks. When we
69:12 determine what the risks are, then we go
69:13 in and look at what the normal use is on
69:14 the device, or even misuse.
69:15 And then we look at the
69:16 labeling, and we look at what the
69:17 indications, the contraindications, the
69:18 warnings, and the precautions. And when
69:19 we look at the risk management, anything
69:20 that is important for the customer to
69:21 know based on the general use of the
69:22 device, we put that in the labeling.
69:23 That's on the normal release.

89:1 - 89:14

Shultz, Gin 01-30-2014 (00:00:37)

03_21_18 Combo Final4.9

89:1 And did you say the G2
89:2 filter was cleared for use sometime in
89:3 2005?
89:4 A. The -- yes, it was -- it was
89:5 cleared for permanent indication.
89:6 Q. Okay. And the G2 filter was
89:7 an extension of the Recovery filter with
89:8 certain design modifications, right?
89:9 A. Yes.
89:10 Q. Okay. And it didn't get
89:11 removal indication for about three years,
89:12 right?
89:13 A. I think it was 2009 it got
89:14 the retrievable indication.

120:22 - 121:10

Shultz, Gin 01-30-2014 (00:00:18)

03_21_18 Combo Final4.10

120:22 Q. There is -- there is
120:23 requirements that are required in design
120:24 development --
121:1 A. Yes.
121:2 Q. -- to make sure this device
121:3 is going to be safe and effective for its

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	121:4 intended use before you put it on the 121:5 market, right? 121:6 A. Yes. 121:7 Q. Okay. And it's never okay 121:8 for a manufacturer to skip those steps 121:9 and then say, " Well, we'll fix it once we 121:10 put it on the market," right?	
121:13 - 121:15	Shultz, Gin 01-30-2014 (00:00:03) 121:13 THE WITNESS: If it's a 121:14 safety issue, I agree with your 121:15 statement.	03_21_18 Combo Final4.11
123:21 - 124:3	Shultz, Gin 01-30-2014 (00:00:16) 123:21 if a manufacturer 123:22 becomes aware that one of its devices has 123:23 substantially higher failure rates than 123:24 its other devices that are used for the 124:1 same purpose, doesn't -- shouldn't the 124:2 manufacturer make consumers aware of 124:3 that?	03_21_18 Combo Final4.12
124:6 - 124:20	Shultz, Gin 01-30-2014 (00:00:38) 124:6 THE WITNESS: We're back to 124:7 the question around the 124:8 risk/benefit. 124:9 So if you have two devices, 124:10 and one has a much -- has a 124:11 greater benefit, there may be 124:12 applications to where you're going 124:13 to go with a potential failure 124:14 mode because the risk/benefit 124:15 analysis shows that it's a benefit 124:16 to have that product out in the 124:17 field. 124:18 It's part of what you look 124:19 at when -- even the FDA looks at 124:20 it on the approval of the devices.	03_21_18 Combo Final4.13
125:11 - 125:15	Shultz, Gin 01-30-2014 (00:00:10) 125:11 Q. And they rely in part 125:12 on the manufacturer to give them a fair 125:13 and balanced disclosure of the risks and 125:14 benefits of the device so they can decide	03_21_18 Combo Final4.14

03_21_18 Combo Final4-Schultz 01-30-14 Booker Depo Designations Final 4

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126:1 - 126:12	<p>125:15 which one to use or not use, right?</p> <p>Shultz, Gin 01-30-2014 (00:00:30)</p> <p>126:1 when we</p> <p>126:2 have a clinical study, which is</p> <p>126:3 prospective and you have good</p> <p>126:4 comparison data, then that's the</p> <p>126:5 type of information that you can</p> <p>126:6 put into your labeling or</p> <p>126:7 disclose, because then it's --</p> <p>126:8 it's very clear what the data is</p> <p>126:9 telling you.</p> <p>126:10 So we have put that into our</p> <p>126:11 labeling when we've had clinical</p> <p>126:12 data.</p>	03_21_18 Combo Final4.15
139:14 - 139:17	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>139:14 In claiming a device as</p> <p>139:15 predicate, Bard is claiming that the</p> <p>139:16 Recovery filter is substantially similar</p> <p>139:17 to the Simon Nitinol filter, isn't it?</p>	03_21_18 Combo Final4.16
139:20 - 139:24	<p>Shultz, Gin 01-30-2014 (00:00:06)</p> <p>139:20 THE WITNESS: It's similar</p> <p>139:21 in the function of the device.</p> <p>139:22 It's similar in the safety and</p> <p>139:23 efficacy. It's safety -- it's</p> <p>139:24 similar in the technology.</p>	03_21_18 Combo Final4.17
140:5 - 140:10	<p>Shultz, Gin 01-30-2014 (00:00:13)</p> <p>140:5 So as physicians who</p> <p>140:6 previously used the Simon Nitinol filter</p> <p>140:7 and now Bard is marketing the Recovery</p> <p>140:8 filter, the presumption was the devices</p> <p>140:9 had equivalent safety, right?</p> <p>140:10 A. Yes.</p>	03_21_18 Combo Final4.18
168:8 - 168:10	<p>Shultz, Gin 01-30-2014 (00:00:06)</p> <p>168:8 Q. Do you agree that an</p> <p>168:9 adulterated product is one that fails to</p> <p>168:10 meet its minimum safety specifications?</p>	03_21_18 Combo Final4.19
168:13 - 168:16	<p>Shultz, Gin 01-30-2014 (00:00:04)</p> <p>168:13 THE WITNESS: It's --</p> <p>168:14 adulterated product would be</p> <p>168:15 product that doesn't meet its</p>	03_21_18 Combo Final4.20

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168:18 - 169:8

168:16 specification period.

Shultz, Gin 01-30-2014 (00:00:30)

03_21_18 Combo Final4.21

168:18 Q. Okay. And --

168:19 A. Of any sort.

168:20 Q. In this case, for the

168:21 filters, that would be migration

168:22 resistance specifications?

168:23 A. The --

168:24 Q. Among others?

169:1 A. It would be -- on

169:2 adulteration, it would be specifications

169:3 of the device. So there's not a release

169:4 test for releasing a batch from migration

169:5 resistance.

169:6 So the migration resistance

169:7 wouldn't be a specification on the

169:8 device.

175:2 - 175:9

Shultz, Gin 01-30-2014 (00:00:11)

03_21_18 Combo Final4.22

175:2 Q. Okay. So you have product

175:3 performance specifications that will lay

175:4 out what the specifications are?

175:5 A. Correct.

175:6 Q. Okay. So if the product

175:7 isn't meeting those specifications, then

175:8 it's adulterated?

175:9 A. Correct.

177:5 - 178:1

Shultz, Gin 01-30-2014 (00:00:28)

03_21_18 Combo Final4.23

177:5 Q. Okay. So as far as if

177:6 you become -- if Bard becomes concerned

177:7 about safety problems with the device --

177:8 A. Yes.

177:9 Q. -- and they want to get that

177:10 information out, there are measures Bard

177:11 can take?

177:12 A. Yes.

177:13 Q. Such as, they can do a field

177:14 correction, right?

177:15 A. Yes.

177:16 Q. They can do a medical device

177:17 notification, right?

03_21_18 Combo Final4-Schultz 01-30-14 Booker Depo Designations Final 4

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	177:18 A. Yes.	
	177:19 Q. They can do a safety alert,	
	177:20 right?	
	177:21 A. Yes.	
	177:22 Q. They can do a recall?	
	177:23 A. Yes.	
	177:24 Q. Okay. Did Bard do any of	
178:4 - 178:5	178:1 those with the Recovery filter? Shultz, Gin 01-30-2014 (00:00:02)	03_21_18 Combo Final4.24
	178:4 THE WITNESS: After -- after	
	178:5 I started with Bard, no.	
178:7 - 178:13	Shultz, Gin 01-30-2014 (00:00:13)	03_21_18 Combo Final4.25
	178:7 Q. Okay. Are you aware of them	
	178:8 doing any of those at any time?	
	178:9 A. I don't remember. I thought	
	178:10 they did.	
	178:11 Q. Okay. They sent out a Dear	
	178:12 Colleague letter? That may be --	
	178:13 A. That's what I was thinking.	
191:7 - 191:13	Shultz, Gin 01-30-2014 (00:00:12)	03_21_18 Combo Final4.26
	191:7 Q. Part of the reason of	
	191:8 looking at failure rates is try to figure	
	191:9 out if indeed yours has substantially	
	191:10 higher than other devices, if that is a	
	191:11 design issue with your product	
	191:12 responsible for that, right?	
	191:13 A. Correct.	
203:16 - 203:17	Shultz, Gin 01-30-2014 (00:00:02)	03_21_18 Combo Final4.27
	203:16 MR. BRENES: Mark this as	
	203:17 Exhibit Number 2.	
204:17 - 204:20	Shultz, Gin 01-30-2014 (00:00:08)	03_21_18 Combo Final4.28
	204:17 Q. Does this appear to be an	SCHULTZDEPOSITIONEXHIBITS-1253092.488.2
	204:18 e-mail from you to Micky Graves, Natalie	
	204:19 Wong and Brian Hudson?	
	204:20 A. Yes.	
206:3 - 206:7	Shultz, Gin 01-30-2014 (00:00:06)	03_21_18 Combo Final4.29
	206:3 Q. Is this likely when there	SCHULTZDEPOSITIONEXHIBITS-1253092.488
	206:4 started being reports for caudal	
	206:5 migration? Is that around the same time	
	206:6 frame?	

03_21_18 Combo Final4-Schultz 01-30-14 Booker Depo Designations Final 4

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206:15 - 206:22	<p>206:7 A. Yes.</p> <p>Shultz, Gin 01-30-2014 (00:00:16)</p> <p>206:15 Q. It says, "How do we compare</p> <p>206:16 to SNF (permanent filters) on migration?"</p> <p>206:17 Do you see that?</p> <p>206:18 A. Yes, I do.</p> <p>206:19 Q. So you were asking for a</p> <p>206:20 comparison of the -- of presumably the G2</p> <p>206:21 filter here, to the SNF, right?</p> <p>206:22 A. Yes.</p>	<p>03_21_18 Combo Final4.30</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.488.3</p>
207:24 - 208:19	<p>Shultz, Gin 01-30-2014 (00:00:42)</p> <p>207:24 Q. Okay. So do you agree that</p> <p>208:1 this appears to be an e-mail from you</p> <p>208:2 stating that you're going to use a</p> <p>208:3 comparison of the safety profile of the</p> <p>208:4 G2 filter versus that of the Simon</p> <p>208:5 Nitinol filter in doing an analysis of</p> <p>208:6 the risks and benefits of the G2 filter,</p> <p>208:7 correct?</p> <p>208:8 A. We're doing an evaluation of</p> <p>208:9 data, and we are looking at comparison to</p> <p>208:10 the Simon Nitinol, and we are looking at</p> <p>208:11 the benefits to risk, yes. I don't know</p> <p>208:12 what the data is though.</p> <p>208:13 Q. And it says, "Determines</p> <p>208:14 options as a company as the benefits to</p> <p>208:15 risks may have changed."</p> <p>208:16 A. Yes.</p> <p>208:17 Q. And you're talking about the</p> <p>208:18 G2 filter, right?</p> <p>208:19 A. I'm assuming, yes.</p>	<p>03_21_18 Combo Final4.31</p> <p>clear</p>
210:12 - 210:19	<p>Shultz, Gin 01-30-2014 (00:00:25)</p> <p>210:12 Q. Is part of the reason Bard</p> <p>210:13 was asking physicians about what their</p> <p>210:14 expectations were for failure rates on</p> <p>210:15 their devices was so that they would know</p> <p>210:16 if further warnings were required?</p> <p>210:17 A. The physician panel that I</p> <p>210:18 was talking to was on the G2, and it was</p> <p>210:19 talking to caudal migration.</p>	<p>03_21_18 Combo Final4.32</p> <p>clear</p>

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210:20 - 211:2	Shultz, Gin 01-30-2014 (00:00:16) 210:20 Q. Okay. And that's fine. 210:21 But -- so what's -- the next part of my 210:22 question is, were you asking physicians 210:23 about their expectations about failure 210:24 rates so you would know, are you in line 211:1 with those failures and whether further 211:2 warnings were required?	03_21_18 Combo Final4.33
211:5 - 211:15	Shultz, Gin 01-30-2014 (00:00:23) 211:5 THE WITNESS: The -- we were 211:6 actually exploring -- it was a 211:7 much broader question -- 211:8 211:9 Q. 211:10 A. -- is what are the 211:11 implications of caudal migration? How 211:12 does that affect the -- the treatment? 211:13 Is this of a -- what's the severity of 211:14 it? So we were actually exploring caudal 211:15 migration in much broader terms.	03_21_18 Combo Final4.34
217:21 - 218:4	Shultz, Gin 01-30-2014 (00:00:20) 217:21 Q. When you were head of 217:22 quality, deciding, you know, what 217:23 additional warnings needed to be given or 217:24 if corrective action needed to be taken, 218:1 were you taking into account this 218:2 physician feedback that had told Bard, 218:3 "No matter what the size of a thrombus, 218:4 filters shouldn't migrate"?	03_21_18 Combo Final4.119
218:7 - 218:19	Shultz, Gin 01-30-2014 (00:00:38) 218:7 THE WITNESS: The -- that is 218:8 part of the feedback. That is the 218:9 design, what we'd want the filter 218:10 to do. So that would be 218:11 considered. 218:12 The fact that the filters 218:13 took the recurring PE rate down to 218:14 such a low level showed that the 218:15 filter did a substantial job or 218:16 function in eliminating the	03_21_18 Combo Final4.35

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226:16 - 226:16	218:17 migration, the PEs. 218:18 So this is -- that is the -- 218:19 that is the intent of the filter. Shultz, Gin 01-30-2014 (00:00:01)	03_21_18 Combo Final4.36
227:4 - 227:13	226:16 Exhibit Number 4. Shultz, Gin 01-30-2014 (00:00:15) 227:4 Ms. Schulz, you mentioned 227:5 there was another physician panel in 227:6 2006; is that right? 227:7 A. There was a physician panel 227:8 that I was involved with. This is -- I'm 227:9 looking at it now. It might be the one 227:10 that I was involved in. 227:11 Q. Does it appear to be this 227:12 one? 227:13 A. I think so.	SCHULTZDEPOSITIONEXHIBITS-1253092.506 03_21_18 Combo Final4.37
227:23 - 228:2	Shultz, Gin 01-30-2014 (00:00:05) 227:23 Q. Have you seen this 227:24 document before? 228:1 A. Actually, I'm not sure I 228:2 have.	03_21_18 Combo Final4.38 clear
228:10 - 228:19	Shultz, Gin 01-30-2014 (00:00:13) 228:10 Q. Do you see where it says, 228:11 "Expect as close as possible to zero - 228:12 everyone." 228:13 Do you see that? 228:14 A. Yes. 228:15 Q. So do you agree that all the 228:16 physicians were saying you should try to 228:17 get a device that has zero fracture rate, 228:18 if possible? 228:19 A. Yes.	03_21_18 Combo Final4.39 SCHULTZDEPOSITIONEXHIBITS-1253092.506.2
228:20 - 228:24	Shultz, Gin 01-30-2014 (00:00:05) 228:20 Q. So in other words, 228:21 like we said earlier, make the device -- 228:22 manufacturers should make the device as 228:23 safe as possible? 228:24 A. Yes.	03_21_18 Combo Final4.40 clear
275:21 - 275:22	Shultz, Gin 01-30-2014 (00:00:02) 275:21 Q. I'll hand you what's	03_21_18 Combo Final4.41

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301:11 - 301:15	<p>275:22 Exhibit 5.</p> <p>Shultz, Gin 01-30-2014 (00:00:15)</p> <p>301:11 Q. Okay. So do you agree or</p> <p>301:12 disagree that statistically significant</p> <p>301:13 higher rates of reported failures between</p> <p>301:14 devices is an important safety signal?</p> <p>301:15 A. Yes.</p>	03_21_18 Combo Final4.42
301:19 - 301:20	<p>Shultz, Gin 01-30-2014 (00:00:02)</p> <p>301:19 Q. You agree to that?</p> <p>301:20 A. Yes.</p>	03_21_18 Combo Final4.43
343:12 - 343:15	<p>Shultz, Gin 01-30-2014 (00:00:02)</p> <p>343:12 MR. BRENES: We're going to</p> <p>343:13 mark what -- hand you what we're</p> <p>343:14 going to mark as Exhibit Number</p> <p>343:15 11.</p>	03_21_18 Combo Final4.44 SCHULTZDEPOSITIONEXHIBITS-1253092.548
343:23 - 344:15	<p>Shultz, Gin 01-30-2014 (00:00:37)</p> <p>343:23 Q. Are you familiar with</p> <p>343:24 documents like this from your time at</p> <p>344:1 Bard?</p> <p>344:2 A. Yes.</p> <p>344:3 Q. And what does it appear to</p> <p>344:4 be?</p> <p>344:5 A. It's a comparison by</p> <p>344:6 complaint type of different filters.</p> <p>344:7 Q. And this was used to track</p> <p>344:8 competitive -- competitive failure rates</p> <p>344:9 between different devices?</p> <p>344:10 A. Yeah, to evaluate rates</p> <p>344:11 across the board.</p> <p>344:12 Q. And to determine if there</p> <p>344:13 was a safety issue with one of Bard's</p> <p>344:14 devices, right?</p> <p>344:15 A. Yes.</p>	03_21_18 Combo Final4.45 clear
344:24 - 345:21	<p>Shultz, Gin 01-30-2014 (00:00:59)</p> <p>344:24 Do you see towards the</p> <p>345:1 bottom of the first page, it says, "Bard</p> <p>345:2 data is from Trackwise, not MAUDE,</p> <p>345:3 through July 2010."</p> <p>345:4 Do you see that?</p> <p>345:5 A. Yes.</p>	03_21_18 Combo Final4.46 SCHULTZDEPOSITIONEXHIBITS-1253092.548.1

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	345:6 Q. Okay. And Trackwise was	
	345:7 Bard's internal complaint tracking	
	345:8 system, right?	
	345:9 A. Yes.	
	345:10 Q. Okay. So this is through	
	345:11 July of 2010.	
	345:12 So as of July of 2010,	
	345:13 there's 179 reported fractures for the	SCHULTZDEPOSITIONEXHIBITS-1253092.548.3
	345:14 Recovery filter, right?	
	345:15 A. Correct.	
	345:16 Q. Okay. And if we compare	clear
	345:17 that to that last memorandum from	
	345:18 November '05, you're looking at over an	
	345:19 additional 120 fractures since that time,	
	345:20 right?	
	345:21 A. Roughly. Yes.	
346:4 - 346:11	Shultz, Gin 01-30-2014 (00:00:15)	03_21_18 Combo Final4.47
	346:4 THE WITNESS: The number is	
	346:5 95. I'm sorry. The difference	
	346:6 between the two, right?	
	346:7 BY MR. BRENES:	
	346:8 Q. 179 minus --	
	346:9 A. 84.	
	346:10 Q. Oh, you're right. Yeah.	
	346:11 Good point.	
352:22 - 353:5	Shultz, Gin 01-30-2014 (00:00:18)	03_21_18 Combo Final4.48
	352:22 Q. No. And then looking at the	
	352:23 G2, the G2 has a reported migration rate	
	352:24 of 1.2 out of every thousand, right?	
	353:1 A. Yes.	
	353:2 Q. Okay. And is any device,	
	353:3 other than a Bard device, even close to	
	353:4 that migration rate?	
	353:5 A. No.	
357:11 - 357:12	Shultz, Gin 01-30-2014 (00:00:02)	03_21_18 Combo Final4.49
	357:11 Q. Let's mark this as	SCHULTZDEPOSITIONEXHIBITS-1253092.550
	357:12 Exhibit 12.	
357:19 - 357:22	Shultz, Gin 01-30-2014 (00:00:09)	03_21_18 Combo Final4.50
	357:19 Q. Do you agree this appears to	SCHULTZDEPOSITIONEXHIBITS-1253092.550.6
	357:20 be an e-mail from Kelly Jones to you	

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	357:21 dated November 30th, 2005?	
	357:22 A. Yes.	
363:7 - 363:13	Shultz, Gin 01-30-2014 (00:00:17)	03_21_18 Combo Final4.51
	363:7 Q. So you agree, again, the	clear
	363:8 Recovery filter's failure rates for	
	363:9 migration, death, fracture, pulmonary	
	363:10 embolism, perforation, are all	
	363:11 substantially higher than the SNF,	
	363:12 correct?	
	363:13 A. Yes.	
378:5 - 378:10	Shultz, Gin 01-30-2014 (00:00:16)	03_21_18 Combo Final4.52
	378:5 Q. Okay. I'm going to hand you	SCHULTZDEPOSITIONEXHIBITS-1253092.559
	378:6 what we'll mark as Exhibit Number --	
	378:7 A. 15.	
	378:8 Q. -- 15. I'm going to hand	
	378:9 you the e-mail and the attachment that	
	378:10 went with it. There you go.	
378:19 - 379:2	Shultz, Gin 01-30-2014 (00:00:22)	03_21_18 Combo Final4.53
	378:19 Q. Please take a minute to	
	378:20 review it. There's also an attachment	
	378:21 for caudal migration, which I didn't give	
	378:22 you. I just want to talk about fractures	
	378:23 right now. You know what? Let's make it	clear
	378:24 complete. I'm going to give you the	
	379:1 caudal migration attachment as well just	
	379:2 so you have all the attachments.	
379:19 - 380:3	Shultz, Gin 01-30-2014 (00:00:25)	03_21_18 Combo Final4.54
	379:19 Q. So do you see the e-mail,	SCHULTZDEPOSITIONEXHIBITS-1253092.559
	379:20 which is from Natalie Wong to you among	SCHULTZDEPOSITIONEXHIBITS-1253092.559.3
	379:21 some others dated May 19th, 2006?	
	379:22 A. Yes.	
	379:23 Q. Okay. And the -- I don't	
	379:24 see a subject, but the attachments are	
	380:1 "G2 caudal summary," and "RNF fracture	
	380:2 report." Right?	
	380:3 A. Yes.	
385:5 - 385:22	Shultz, Gin 01-30-2014 (00:00:49)	03_21_18 Combo Final4.55
	385:5 Q. Okay. And does it appear	SCHULTZDEPOSITIONEXHIBITS-1253092.602.1
	385:6 that Bard is contemplating some	
	385:7 additional corrective action regarding	

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	385:8 the Recovery filter in this PowerPoint?	
	385:9 A. Yes.	
	385:10 Q. And one of those things is	
	385:11 potentially a customer letter, right?	
	385:12 A. Yes.	
	385:13 Q. Okay. Content, it says,	
	385:14 "Notify fracture rate. Standard of care	SCHULTZDEPOSITIONEXHIBITS-1253092.602.3
	385:15 applies, risk/benefit compared to	
	385:16 competitors."	
	385:17 Do you see that?	
	385:18 A. Yes.	
	385:19 Q. So it appears to be	
	385:20 contemplating the potential disclosure of	
	385:21 competitive fracture rates so doctors can	
	385:22 do risk/benefit analysis, right?	
386:1 - 386:15	Shultz, Gin 01-30-2014 (00:00:19)	03_21_18 Combo Final4.56
	386:1 THE WITNESS: For the	
	386:2 content, the risk/benefit was that	
	386:3 we would provide the risk/benefit	
	386:4 and compare to competitors. What	
	386:5 they do with it was something	
	386:6 else.	
	386:7 BY MR. BRENES:	clear
	386:8 Q. Got it. So in other words	
	386:9 you could -- providing your analysis of	
	386:10 what the risks and the benefits are of	
	386:11 the filter --	
	386:12 A. Right.	
	386:13 Q. -- in respect to competitive	
	386:14 failure rates?	
	386:15 A. Yes.	
387:19 - 388:1	Shultz, Gin 01-30-2014 (00:00:12)	03_21_18 Combo Final4.57
	387:19 Q. Now, in fairness let's look	
	387:20 at the cons. "Does not provide	
	387:21 additional information that physician	
	387:22 does not already know."	
	387:23 Do you see that? Do you see	
	387:24 that?	
	388:1 A. Yes, I do.	
388:2 - 388:16	Shultz, Gin 01-30-2014 (00:00:32)	03_21_18 Combo Final4.58

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	388:2 Q. Okay. Now, physicians don't	
	388:3 know -- don't necessarily know what	
	388:4 Bard's complaint files reveal, right?	
	388:5 A. Correct. They don't have	
	388:6 specific information on the complaint	
	388:7 files.	
	388:8 Q. And they -- and Bard never	
	388:9 provided them with competitive failure	
	388:10 rate information, right, as far as you	
	388:11 know?	
	388:12 A. As far as I know.	
	388:13 Q. And you would certainly	
	388:14 agree that Bard's own complaint files and	
	388:15 sales rate information is more reliable	
	388:16 than general MAUDE data, right?	
388:19 - 388:21	Shultz, Gin 01-30-2014 (00:00:05)	03_21_18 Combo Final4.59
	388:19 THE WITNESS: Bard's	
	388:20 complaint data is more accurate	
	388:21 than the MAUDE database.	
388:23 - 389:19	Shultz, Gin 01-30-2014 (00:00:54)	03_21_18 Combo Final4.60
	388:23 Q. The second con is,	
	388:24 "Notifying patients that may never have	
	389:1 complications."	
	389:2 Do you know what they mean	
	389:3 by that?	
	389:4 A. So the -- in some of the	
	389:5 data analysis, the majority of the	
	389:6 patients were asymptomatic for fractures.	
	389:7 And so when they -- similar to the issue	
	389:8 with monitoring for breast cancer, that	
	389:9 people will have false negative, so they	
	389:10 start reacting, and they have additional	
	389:11 healthcare. It causes additional issues.	
	389:12 So, you know, the fact that	
	389:13 most of the patients were asymptomatic	
	389:14 and the fact that they start notifying	
	389:15 them, then you're going to have patients	
	389:16 trying to figure out what that means or	
	389:17 not means and that type of issue --	
	389:18 Q. Okay.	

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394:15 - 394:23	<p>389:19 A. -- is more of that line.</p> <p>Shultz, Gin 01-30-2014 (00:00:19)</p> <p>394:15 Q. Okay. Go to the next page,</p> <p>394:16 "Potential next steps," and, "Recall</p> <p>394:17 existing inventory." Do you see that?</p> <p>394:18 A. Yes.</p> <p>394:19 Q. So it appears Bard was</p> <p>394:20 contemplating the possibility of</p> <p>394:21 recalling the Recovery filter, even in</p> <p>394:22 '06, right?</p> <p>394:23 A. Yes.</p>	<p>03_21_18 Combo Final4.61</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253692.603.11</p>
394:24 - 395:2	<p>Shultz, Gin 01-30-2014 (00:00:05)</p> <p>394:24 Q. Okay. The pro is, "Update</p> <p>395:1 inventory with better performing filter,"</p> <p>395:2 right?</p>	<p>03_21_18 Combo Final4.62</p> <p>clear</p>
395:3 - 395:3	<p>Shultz, Gin 01-30-2014 (00:00:01)</p> <p>395:3 A. Yes.</p>	03_21_18 Combo Final4.63
395:4 - 395:7	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>395:4 Q. Shouldn't that be a</p> <p>395:5 company's goal, is always get a patient</p> <p>395:6 the best and the safest device a company</p> <p>395:7 has?</p>	03_21_18 Combo Final4.64
395:10 - 395:18	<p>Shultz, Gin 01-30-2014 (00:00:13)</p> <p>395:10 THE WITNESS: That --</p> <p>395:11 that's -- if you look at the</p> <p>395:12 iterations of the filter, that is</p> <p>395:13 the desire of the product all the</p> <p>395:14 way through.</p> <p>395:15 BY MR. BRENES:</p> <p>395:16 Q. Okay.</p> <p>395:17 A. We've -- the performance has</p> <p>395:18 improved with every iteration.</p>	03_21_18 Combo Final4.65
399:21 - 400:9	<p>Shultz, Gin 01-30-2014 (00:00:20)</p> <p>399:21 Bard didn't recall the</p> <p>399:22 Recovery filter, correct?</p> <p>399:23 A. Correct.</p> <p>399:24 Q. Bard didn't suggest that</p> <p>400:1 physicians explant the Recovery filter,</p> <p>400:2 correct?</p> <p>400:3 A. Correct.</p>	03_21_18 Combo Final4.66

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	400:4 Q. And they basically took	
	400:5 Option 3, which was no field action --	
	400:6 A. Correct.	
	400:7 Q. -- regarding the Recovery	
	400:8 filter, correct?	
	400:9 A. Correct.	
406:17 - 406:19	Shultz, Gin 01-30-2014 (00:00:06)	03_21_18 Combo Final4.67
	406:17 Q. What was the benefit of the	
	406:18 G2 filter over the Simon Nitinol filter	
	406:19 during that time period?	
406:22 - 407:2	Shultz, Gin 01-30-2014 (00:00:13)	03_21_18 Combo Final4.68
	406:22 THE WITNESS: When I had	
	406:23 first started with Bard, the G2,	
	406:24 the physician community was	
	407:1 viewing it as an RNF type of	
	407:2 device.	
412:12 - 412:14	Shultz, Gin 01-30-2014 (00:00:05)	03_21_18 Combo Final4.69
	412:12 Q. as	
	412:13 the head of quality at Bard at that time,	
	412:14 it was okay to keep selling the G2?	
412:17 - 412:23	Shultz, Gin 01-30-2014 (00:00:12)	03_21_18 Combo Final4.70
	412:17 THE WITNESS: The	
	412:18 customer -- the customer wanted	
	412:19 the G2. They found that that was	
	412:20 a benefit to them to buy the G2.	
	412:21 They had the option of buying the	
	412:22 Simon Nitinol. So the customer,	
	412:23 as their own judge, chose the G2.	
413:7 - 413:12	Shultz, Gin 01-30-2014 (00:00:07)	03_21_18 Combo Final4.71
	413:7 THE WITNESS: The customer	
	413:8 that used the device knew what	
	413:9 their failure rate was and	
	413:10 continued to use it even --	
	413:11 BY MR. BRENES:	
	413:12 Q. That wasn't my question.	
415:22 - 416:2	Shultz, Gin 01-30-2014 (00:00:10)	03_21_18 Combo Final4.72
	415:22 Q. Simply, did -- are you aware	
	415:23 of Bard -- whether or not Bard shared	
	415:24 information with the doctors about the	
	416:1 comparative failure rates between Simon	

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416:6 - 416:7	416:2 Nitinol filter and the G2 filter? Shultz, Gin 01-30-2014 (00:00:01)	03_21_18 Combo Final4.73
417:9 - 417:11	416:6 THE WITNESS: Not to my 416:7 knowledge. Shultz, Gin 01-30-2014 (00:00:04)	03_21_18 Combo Final4.74
417:14 - 418:3	417:9 Q. Okay. So at some point, did 417:10 you become aware that there were 417:11 stability problems with the G2 filter? Shultz, Gin 01-30-2014 (00:00:25)	03_21_18 Combo Final4.75
418:6 - 418:17	417:14 THE WITNESS: The G2 filter 417:15 on launch, we monitored migration, 417:16 and that's where we identified 417:17 caudal migration. 417:18 BY MR. BRENES: 417:19 Q. And did you also become 417:20 aware that there were problems with the 417:21 device tilting? 417:22 A. There was complaints of it 417:23 tilting as well. 417:24 Q. Okay. And did you also 418:1 become aware of fracture rates that were 418:2 higher than for the Simon Nitinol filter 418:3 for the G2 filter? Shultz, Gin 01-30-2014 (00:00:14)	03_21_18 Combo Final4.76
422:18 - 422:21	418:6 THE WITNESS: We monitored 418:7 the fracture rates. 418:8 BY MR. BRENES: 418:9 Q. And those were higher with 418:10 the G2 filter than with the Simon Nitinol 418:11 filter, correct? 418:12 A. Yes. We've gone through the 418:13 exhibits. Yes. 418:14 Q. And the migration rates were 418:15 higher for the G2 filter than the Simon 418:16 Nitinol filter, correct? 418:17 A. Yes. Shultz, Gin 01-30-2014 (00:00:08)	03_21_18 Combo Final4.77
	422:18 Now, in respect to G2, are 422:19 you aware that the G2 was being 422:20 redesigned because of the caudal	

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422:24 - 423:2	422:21 migration problem? Shultz, Gin 01-30-2014 (00:00:03) 422:24 THE WITNESS: The G2 was 423:1 being redesigned, and we were 423:2 looking at caudal migration.	03_21_18 Combo Final4.78
431:14 - 431:17	Shultz, Gin 01-30-2014 (00:00:11) 431:14 Q. Okay. Did Bard send a 431:15 customer letter notifying physicians that 431:16 there was an unexpected level of reported 431:17 caudal migrations?	03_21_18 Combo Final4.79
431:20 - 431:20	Shultz, Gin 01-30-2014 (00:00:00) 431:20 THE WITNESS: No.	03_21_18 Combo Final4.80
432:13 - 432:14	Shultz, Gin 01-30-2014 (00:00:03) 432:13 Q. Okay. And what do you have 432:14 to say about that e-mail?	03_21_18 Combo Final4.81
433:1 - 433:4	Shultz, Gin 01-30-2014 (00:00:07) 433:1 THE WITNESS: Dr. Ciavarella 433:2 wasn't at the division. He didn't 433:3 understand a lot of the details of 433:4 it.	03_21_18 Combo Final4.82
434:19 - 434:20	Shultz, Gin 01-30-2014 (00:00:03) 434:19 MR. BRENES: We're going to 434:20 mark this as Exhibit Number 17.	03_21_18 Combo Final4.83 SCHULTZDEPOSITIONEXHIBITS-1253092.642
435:4 - 436:5	Shultz, Gin 01-30-2014 (00:01:01) 435:4 Q. Okay. And this appears to 435:5 be a document or an e-mail from you to a 435:6 number of people at Bard, right? 435:7 A. Yes. 435:8 Q. And it appears to be 435:9 discussing caudal migrations with the G2 435:10 filter, correct? 435:11 A. Yes. 435:12 Q. Okay. The first page under 435:13 "discussion points," do you see the 435:14 bullet point -- I think it's Number 3. 435:15 It says, "Project approved to redesign 435:16 and develop caudal movement test method." 435:17 Do you see that? 435:18 A. Yes. 435:19 Q. Okay. So does this refresh	03_21_18 Combo Final4.84 SCHULTZDEPOSITIONEXHIBITS-1253092.642.1 SCHULTZDEPOSITIONEXHIBITS-1253092.642.2 SCHULTZDEPOSITIONEXHIBITS-1253092.642.3

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Page/Line	Source	ID
	435:20 your recollection as to whether or not 435:21 there was a test for caudal migration 435:22 before the G2 filter went on the market? 435:23 A. The -- so there was a test 435:24 method for caudal migration that needed 436:1 to be made. 436:2 Q. Okay. So there wasn't one 436:3 before? 436:4 A. There -- there may not have 436:5 been, or it may not have been adequate.	clear
440:4 - 440:5	Shultz, Gin 01-30-2014 (00:00:02)	03_21_18 Combo Final4.85
	440:4 Q. I'm going to hand you what 440:5 we'll mark as Exhibit 19. Please take a	SCHULTZDEPOSITIONEXHIBITS-1253092.647
440:12 - 440:23	Shultz, Gin 01-30-2014 (00:00:26)	03_21_18 Combo Final4.86
	440:12 Q. So do you agree that it 440:13 appears to be an e-mail dated May 10, 440:14 2006, between Bard personnel regarding a 440:15 proposed response to FDA questions 440:16 regarding a complaint? 440:17 A. It's in response to an FDA 440:18 question -- yeah, it's about a complaint: 440:19 It's got a manufacturing report number. 440:20 Q. Okay. And the e-mail is 440:21 dated -- I may have said this -- is dated 440:22 May 10, 2006, right? 440:23 A. Yes.	SCHULTZDEPOSITIONEXHIBITS-1253092.647.1
441:5 - 442:2	Shultz, Gin 01-30-2014 (00:00:51)	03_21_18 Combo Final4.87
	441:5 Q. It says, "As defined in the 441:6 design failure modes and effects analysis 441:7 (DFMEA) for this product, the expected 441:8 frequency of occurrence for caudal 441:9 migration is less than or equal to 441:10 0.05 percent." 441:11 A. Yes. 441:12 Q. Okay. And that is five out 441:13 of every 10,000? 441:14 A. Yes. 441:15 Q. And then it continues, "The 441:16 observed frequency of occurrence is 441:17 .129 percent, as of April 30, 2006,"	SCHULTZDEPOSITIONEXHIBITS-1253092.648.3

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441:18 right?

441:19 A. Correct.

441:20 Q. Okay. And that -- so that's

441:21 1.2 out of every thousand, right?

441:22 A. Correct.

441:23 Q. Okay. So we agree that

441:24 caudal migration had exceeded Bard's

442:1 expected occurrence levels?

442:2 A. Correct.

442:6 - 442:14

Shultz, Gin 01-30-2014 (00:00:20)

03_21_18 Combo Final4.88

442:6 Q. Exhibit Number 20, again,

442:7 just because of time concerns, let me

442:8 address some specific things.

442:9 So does this appear to be an

442:10 e-mail from Tracy Estrada, dated

442:11 April 1st, 2010, to some other people at

442:12 Bard with an attachment, "Eclipse Anchor

442:13 Idea POA Final," right?

442:14 A. Yes.

444:7 - 444:15

Shultz, Gin 01-30-2014 (00:00:14)

03_21_18 Combo Final4.89

444:7 Q. Look under -- actually,

444:8 "situation." Do you see where it says,

444:9 "Physician perception is that design

444:10 sacrifices were made to optional filters

444:11 that permit retrievability, but also

444:12 allow for a higher rate of movement or

444:13 migration."

444:14 Do you see that?

444:15 A. Yes.

445:17 - 446:1

Shultz, Gin 01-30-2014 (00:00:22)

03_21_18 Combo Final4.90

445:17 Q. Either from speaking with

445:18 physicians, from doing surveys, what have

445:19 you?

445:20 A. I don't -- I don't ever

445:21 remember a physician have a perception of

445:22 that. But I do know that there was

445:23 differences in the way a retrievable or

445:24 optional filter would perform than a

446:1 permanent filter.

446:14 - 447:6

Shultz, Gin 01-30-2014 (00:00:30)

03_21_18 Combo Final4.91

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446:14 Q. Okay. Look at "problems"

446:15 for me, where it says, "Filter movement

446:16 may lead to tilting, undesirable cava

446:17 wall incorporation, increased risk of

446:18 filter fracture and vena cava

446:19 penetration."

446:20 Do you see that?

446:21 A. Yes.

446:22 Q. Is that consistent with your

446:23 understanding that movement may lead to

446:24 tilting?

447:1 A. Yes. That was a hypothesis,

447:2 that the movement would cause the

447:3 tilting.

447:4 Q. Was it consistent with your

447:5 understanding that movement could lead to

447:6 penetration into the vena cava?

447:9 - 447:19

Shultz, Gin 01-30-2014 (00:00:22)

447:9 THE WITNESS: It was my

447:10 understanding that tilting could

447:11 lead to penetration.

447:12 BY MR. BRENES:

447:13 Q. Okay. And was it your

447:14 understanding that movement could lead to

447:15 filter fracture?

447:16 A. More back to the tilted,

447:17 that if you had a tilted filter, then

447:18 you're going to have uneven stresses on

447:19 it. And that would lead to it.

448:7 - 448:8

Shultz, Gin 01-30-2014 (00:00:02)

448:7 A. That that was a potential

448:8 contributor to it.

448:9 - 448:13

Shultz, Gin 01-30-2014 (00:00:10)

448:9 Q. So maybe the better

448:10 way to ask it is, was it your

448:11 understanding that tilting could lead to

448:12 increased risk of perforation and

448:13 fracture?

448:16 - 448:18

Shultz, Gin 01-30-2014 (00:00:04)

448:16 THE WITNESS: Yes.

SCHULTZDEPOSITIONEXHIBITS-
1253092.652.2

clear

03_21_18 Combo Final4.92

03_21_18 Combo Final4.93

03_21_18 Combo Final4.94

03_21_18 Combo Final4.95

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448:21 - 449:18	<p>448:17 BY MR. BRENES:</p> <p>448:18 Q. Yes to both?</p> <p>Shultz, Gin 01-30-2014 (00:00:42)</p> <p>448:21 THE WITNESS: Yes.</p> <p>448:22 BY MR. BRENES:</p> <p>448:23 Q. Okay. Look under</p> <p>448:24 "hypothesis," where it says, "The</p> <p>449:1 addition of caudal anchors to Eclipse</p> <p>449:2 filters will reduce caudal migrations."</p> <p>449:3 Do you see that?</p> <p>449:4 A. Yes.</p> <p>449:5 Q. Okay. "Reduce complaints</p> <p>449:6 for tilt," do you see that?</p> <p>449:7 A. Yes.</p> <p>449:8 Q. "Reduce complaints for</p> <p>449:9 fracture," do you see that?</p> <p>449:10 A. "Reduce complaints for tilt,</p> <p>449:11 fracture and penetration."</p> <p>449:12 Q. Okay. Secondary to -- here</p> <p>449:13 it says caudal migration, right?</p> <p>449:14 A. Yes.</p> <p>449:15 Q. But the main thing was</p> <p>449:16 reduce the incidence, in your mind of</p> <p>449:17 tilting, which then would -- could</p> <p>449:18 potentially lead to those issues, right?</p>	<p>03_21_18 Combo Final4.96</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.652.3</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.653.1</p>
449:21 - 449:23	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>449:21 THE WITNESS: The tilt to me</p> <p>449:22 was more significant than the</p> <p>449:23 caudal.</p>	<p>03_21_18 Combo Final4.97</p>
450:9 - 450:20	<p>Shultz, Gin 01-30-2014 (00:00:33)</p> <p>450:9 Q. Yeah. Look for me on the</p> <p>450:10 page ending in 860 under "strategic</p> <p>450:11 rationale." Second sentence, do you see</p> <p>450:12 where it says, "Eclipse with caudal</p> <p>450:13 anchors would be positioned as the</p> <p>450:14 premier optional filter with existing and</p> <p>450:15 new customers, infuse enthusiasm for the</p> <p>450:16 product into the sales team, and address</p> <p>450:17 quality issues with the predicate filter</p> <p>450:18 products."</p>	<p>03_21_18 Combo Final4.98</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.1</p>

Page/Line	Source	ID
451:16 - 452:1	<p>450:19 Do you see that?</p> <p>450:20 A. Yes.</p> <p>Shultz, Gin 01-30-2014 (00:00:26)</p> <p>451:16 Q. Continuing, "The performance</p> <p>451:17 issues of BPV optional filters have led</p> <p>451:18 to sales attrition, and these</p> <p>451:19 complications overshadow the unique</p> <p>451:20 long-term retrievability of these</p> <p>451:21 products."</p> <p>451:22 Were you aware in this time</p> <p>451:23 frame, April 2010, that the performance</p> <p>451:24 issues with the -- Bard's filters was</p> <p>452:1 leading to sales attrition?</p>	<p>03_21_18 Combo Final4.99</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.2</p>
452:4 - 452:13	<p>Shultz, Gin 01-30-2014 (00:00:27)</p> <p>452:4 THE WITNESS: There was a --</p> <p>452:5 across the industry, of the filter</p> <p>452:6 product lines, the sales were</p> <p>452:7 either not growing at the rate or</p> <p>452:8 growing at a slower rate or</p> <p>452:9 staying flat.</p> <p>452:10 And there was general</p> <p>452:11 communications across many</p> <p>452:12 regulatory industries around</p> <p>452:13 filters.</p>	<p>03_21_18 Combo Final4.100</p> <p>clear</p>
452:15 - 452:18	<p>Shultz, Gin 01-30-2014 (00:00:05)</p> <p>452:15 Q. This isn't talking about</p> <p>452:16 other people's products. This is talking</p> <p>452:17 about Bard's products, right?</p> <p>452:18 A. Yep.</p>	<p>03_21_18 Combo Final4.101</p>
453:8 - 453:13	<p>Shultz, Gin 01-30-2014 (00:00:09)</p> <p>453:8 Q. Okay. Do you see where it</p> <p>453:9 continues, "These experiences have</p> <p>453:10 created a lukewarm opinion of the product</p> <p>453:11 with the sales team and resulted in lost</p> <p>453:12 business opportunities"?</p> <p>453:13 A. Yes.</p>	<p>03_21_18 Combo Final4.102</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.3</p>
453:22 - 454:9	<p>Shultz, Gin 01-30-2014 (00:00:24)</p> <p>453:22 Q. It continues, "This project</p> <p>453:23 should not only reduce physical</p> <p>453:24 complications but should also help</p>	<p>03_21_18 Combo Final4.103</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.4</p>

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	454:1 address psychological reservations, both	
	454:2 in the sales teams and with customers	
	454:3 regarding BPV optional filters."	
	454:4 Do you see that?	
	454:5 A. Yes.	
	454:6 Q. Okay. So adding caudal	
	454:7 anchors to Bard's optional filters was --	
	454:8 it was believed that it was going to	
	454:9 reduce physical complications, correct?	
454:12 - 454:14	Shultz, Gin 01-30-2014 (00:00:03)	03_21_18 Combo Final4.104
	454:12 THE WITNESS: The POA	
	454:13 statement -- has that statement in	
	454:14 it, yes.	
454:16 - 455:2	Shultz, Gin 01-30-2014 (00:00:25)	03_21_18 Combo Final4.105
	454:16 Q. Okay. Do you have any	clear
	454:17 recollection of why -- why caudal anchors	
	454:18 were being added to the filters?	
	454:19 A. The -- to give the filter a	
	454:20 positional stability so you would reduce	
	454:21 tilting and other complications that come	
	454:22 from it.	
	454:23 Q. That result from tilting?	
	454:24 A. That result from tilting.	
	455:1 Q. Such as fracture?	
	455:2 A. And perforation.	
455:10 - 455:11	Shultz, Gin 01-30-2014 (00:00:03)	03_21_18 Combo Final4.106
	455:10 Q. Okay. I'm going to hand you	SCHULTZDEPOSITIONEXHIBITS-1253092.656.9
	455:11 what we'll mark as Exhibit Number 21.	
456:1 - 456:6	Shultz, Gin 01-30-2014 (00:00:11)	03_21_18 Combo Final4.107
	456:1 Q. Do you agree that this	
	456:2 appears to be an e-mail with an	SCHULTZDEPOSITIONEXHIBITS-1253092.656.2
	456:3 attachment from Brian Hudson to some	
	456:4 Bard -- two Bard employees, dated	
	456:5 June 28, 2011?	
	456:6 A. Yes.	
457:6 - 457:10	Shultz, Gin 01-30-2014 (00:00:11)	03_21_18 Combo Final4.108
	457:6 Q. Okay. Under subject, it	
	457:7 says, "Fracture talking points." And	
	457:8 attachment, it says, "Filter data	
	457:9 6/27/11," right?	

03_21_18 Combo Final4-Schultz 01-30-14 Booker Depo Designations Final 4

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457:19 - 457:22	<p>457:10 A. Yes.</p> <p>Shultz, Gin 01-30-2014 (00:00:09)</p> <p>457:19 Q. For the Simon Nitinol</p> <p>457:20 filter, there were 80,187 devices sold,</p> <p>457:21 right?</p> <p>457:22 A. Yes.</p>	<p>03_21_18 Combo Final4.109</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.659.5</p>
458:5 - 458:9	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>458:5 Q. And the Simon Nitinol</p> <p>458:6 filter, out of the 80,000-plus units</p> <p>458:7 sold, had eight fracture complaints,</p> <p>458:8 right?</p> <p>458:9 A. Yes.</p>	<p>03_21_18 Combo Final4.110</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.659.6</p>
459:20 - 460:2	<p>Shultz, Gin 01-30-2014 (00:00:21)</p> <p>459:20 Q. Okay. Look for me at the G2</p> <p>459:21 filter. It's got 156 fracture complaints</p> <p>459:22 and it had a -- it looks like 126,369</p> <p>459:23 devices sold, right?</p> <p>459:24 A. Yes.</p> <p>460:1 Q. And its rate is</p> <p>460:2 .123 percent, right?</p>	<p>03_21_18 Combo Final4.111</p> <p>clear</p>
460:3 - 460:6	<p>Shultz, Gin 01-30-2014 (00:00:06)</p> <p>460:3 A. Yes.</p> <p>460:4 Q. So it's 12.3 out of every</p> <p>460:5 thousand, right?</p> <p>460:6 A. Yes.</p>	<p>03_21_18 Combo Final4.112</p>
460:20 - 461:6	<p>Shultz, Gin 01-30-2014 (00:00:27)</p> <p>460:20 The rate for -- according to</p> <p>460:21 this document, for the G2 for fracture</p> <p>460:22 complaints was 12 times higher than that</p> <p>460:23 for the Simon Nitinol filter, correct?</p> <p>460:24 A. Correct.</p> <p>461:1 Q. Okay. Now, again, as far as</p> <p>461:2 you're aware, failure rate information</p> <p>461:3 regarding the higher reported failure</p> <p>461:4 rates for the Recovery and G2 filter</p> <p>461:5 versus the Simon Nitinol filter was never</p> <p>461:6 shared with consumers, correct?</p>	<p>03_21_18 Combo Final4.113</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.659.19</p>
461:9 - 461:9	<p>Shultz, Gin 01-30-2014 (00:00:01)</p> <p>461:9 THE WITNESS: Correct.</p>	<p>03_21_18 Combo Final4.114</p>
467:23 - 468:15	<p>Shultz, Gin 01-30-2014 (00:00:40)</p>	<p>03_21_18 Combo Final4.115</p>

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467:23 Q. Are you aware of the
 467:24 Cantwell study where he compared the
 468:1 Recovery and G2 filter?
 468:2 A. I'm sure I reviewed --
 468:3 Q. In 2009?
 468:4 A. I'm sure I would have
 468:5 reviewed it.
 468:6 Q. And he found a -- a
 468:7 migration rate of 46.7 percent for the G2
 468:8 filter?
 468:9 A. I'm sure I read it.
 468:10 Q. Okay.
 468:11 A. And whatever numbers you're
 468:12 reading off, I'm sure they're there.
 468:13 Q. Did a 40 percent --
 468:14 46 percent migration rate exceed Bard's
 468:15 expected migration rate?

468:18 - 469:13

Shultz, Gin 01-30-2014 (00:00:44)

468:18 THE WITNESS: The details of
 468:19 the report, I don't remember. But
 468:20 from what you've stated of
 468:21 46 percent, if it was true, it
 468:22 would exceed.

468:23 BY MR. BRENES:

468:24 Q. Okay. And do you know, did
 469:1 Bard send this -- or send out a warning
 469:2 letter to consumers regarding the
 469:3 findings of Dr. Cantwell?
 469:4 A. Bard did not send out a
 469:5 warning letter.

469:6 Q. Okay. And do you know he
 469:7 wrote that, "Caudal migration is thought
 469:8 to be rare and that the incidence
 469:9 observed with caudal migration of the G2
 469:10 filter in this case was beyond what had
 469:11 been previously been reported"?

469:12 A. I'm sure what you're reading
 469:13 is correct, so...

469:14 - 469:17

Shultz, Gin 01-30-2014 (00:00:09)

469:14 Q. Was that concerning

clear

03_21_18 Combo Final4.116

03_21_18 Combo Final4.117

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469:22 - 470:1	<p>469:15 to Bard that this study had found failure 469:16 rates beyond what had previously been 469:17 reported in the medical literature? Shultz, Gin 01-30-2014 (00:00:09) 469:22 A. We would evaluate it to 469:23 determine if the data was valid. We 469:24 would fill out a complaint. We would 470:1 investigate it.</p>	03_21_18 Combo Final4.118
<p>Plaintiffs Designations = 00:23:22 Defense Designations = 00:09:30 Total Time = 00:32:52</p> <p>Documents Shown SCHULTZDEPOSITIONEXHIBITS-1253092</p>		

EXHIBIT K

Designation Run Report

Altonaga 10-22-13 Booker Depo Designations Final2.1

Altonaga, Bill 10-22-2013

Plaintiffs Designations 00:13:20

Defense Designations 00:04:27

Their Conditionals 00:00:18

Total Time 00:18:05



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7:15 - 8:4	Altonaga, Bill 10-22-2013 (00:00:48) 7:15 Q. All right. It's my understanding that you are 7:16 a medical doctor, certainly, by education? 7:17 A. Correct. 7:18 Q. And if you would, highlight your educational 7:19 background for us. 7:20 A. Okay. I went to college here in Miami, and 7:21 then I went to CETEC University in the Dominican 7:22 Republic where I got my medical degree. Subsequent to 7:23 that, I went back and got my second doctorate in 7:24 optometry in Boston at the New England College of 8:1 Optometry, practiced primarily as a clinical optometrist 8:2 for 19 years. And like in 2005, I believe, I took a 8:3 career change, and I started working for Alcon 8:4 Laboratories in the medical industry.	03_21_18 combo final2_1.1
8:11 - 8:16	Altonaga, Bill 10-22-2013 (00:00:16) 8:11 Q. Do you have what we typically know 8:12 about here in the States as a four-year bachelor's 8:13 degree or a four-year degree at all? 8:14 A. No, sir, it's not a four-year degree. It's 8:15 undergraduate courses that allowed me to enter the 8:16 program that they had in the Dominican Republic.	03_21_18 combo final2_1.2
14:4 - 14:9	Altonaga, Bill 10-22-2013 (00:00:15) 14:4 Q. All right. And just so we all understand one 14:5 another, while you have a medical doctor degree from 14:6 CETEC in the Dominican Republic, you are not a licensed 14:7 medical doctor in Florida or the United States; is that 14:8 correct? 14:9 A. That is correct.	03_21_18 combo final2_1.3
33:17 - 34:10	Altonaga, Bill 10-22-2013 (00:00:49) 33:17 Q. And what is the underlying purpose behind 33:18 postmarket surveillance? 33:19 A. To gather document information, to investigate 33:20 the event that has occurred, or alleged to have 33:21 occurred, and determine the root cause of the problem, 33:22 and, if necessary, implement changes to try to mitigate 33:23 it from happening again. 33:24 Q. All right. And is there an ultimate safety 34:1 purpose behind that postmarket surveillance concept? 34:2 A. Sure.	03_21_18 combo final2_1.4

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34:3 Q. What is that ultimate safety purpose?

34:4 A. To assure that the devices are as safe as they

34:5 possibly can be.

34:6 Q. What about from the standpoint of the public,

34:7 what is the underlying safety purpose behind postmarket

34:8 surveillance?

34:9 A. To make sure that the manufacturers are aware

34:10 of things that could harm people.

71:24 - 72:5

Altonaga, Bill 10-22-2013 (00:00:15)

03_21_18 combo final2_1.5

71:24 Q. All right. Are you familiar with the term

72:1 "misbranding"?

72:2 A. I am.

72:3 Q. What is it?

72:4 A. Misbranding means that you can mislead or

72:5 provide information that is false or misleading.

72:11 - 73:23

Altonaga, Bill 10-22-2013 (00:01:35)

03_21_18 combo final2_1.6

72:11 Q. In the context of promotional materials, does

72:12 misbranding apply to those types of materials, the

72:13 concept?

72:14 A. Yes, it could.

72:15 Q. Does misbranding apply to posters?

72:16 A. Yes, it could.

72:17 Q. Does it apply to tags?

72:18 A. Yes, it could.

72:19 Q. Does it apply to pamphlets?

72:20 A. Yes, it could.

72:21 Q. Circulars?

72:22 A. Yes, it could.

72:23 Q. Booklets?

72:24 A. Yes, it could.

73:1 Q. Brochures?

73:2 A. Yes, it could.

73:3 Q. Instruction books?

73:4 A. Yes, it could.

73:5 Q. Direction sheets?

73:6 A. Yes, it could.

73:7 Q. Information on a manufacturer's website?

73:8 A. Yes, it could.

73:9 Q. Okay. So if, for example, Bard, in any one of

73:10 those mediums, said that the failure rate, for example,

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73:11 for migration of the Recovery filter is similar to
73:12 competitor filters and that wasn't true, would that be
73:13 an example of misbranding?

73:14 A. It could be.

73:15 Q. Could be or would be?

73:16 A. The way you posed the question, if it were
73:17 untrue?

73:18 Q. If it was false or misleading.

73:19 A. If it's unsubstantiated, then it would be false
73:20 or misleading.

73:21 Q. Well, when you say unsubstantiated --

73:22 A. Meaning you don't have the facts to support
73:23 that particular claim.

86:2 - 86:10

Altonaga, Bill 10-22-2013 (00:00:27)

03_21_18 combo final2_1.7

86:2 Q. Do you agree that the performance failures of
86:3 marketed medical devices can pose serious risks to
86:4 public health?

86:5 A. Yes.

86:6 Q. Do you agree that recalls serve both to correct
86:7 defects in current and future devices and to notify
86:8 users of potential risks and steps to minimize the
86:9 impact of failure -- of device failure or malfunction?

86:10 A. Yes.

87:2 - 87:4

Altonaga, Bill 10-22-2013 (00:00:07)

03_21_18 combo final2_1.8

87:2 Q. Well, I mean, I'm asking you your
87:3 understanding. Would that include a medical device that
87:4 fails to perform as intended?

87:6 - 87:6

Altonaga, Bill 10-22-2013 (00:00:02)

03_21_18 combo final2_1.9

87:6 A. I would think that that is possible, yes.

87:18 - 87:22

Altonaga, Bill 10-22-2013 (00:00:19)

03_21_18 combo final2_1.10

87:18 Q. All right. In order to come to the conclusion
87:19 as to whether a device should or should not be recalled,
87:20 would it be important to consider the failure mode
87:21 evaluation and the severity of harm evaluation?

87:22 A. Yes.

90:15 - 90:22

Altonaga, Bill 10-22-2013 (00:00:23)

03_21_18 combo final2_1.11

90:15 Q. Can we agree, however, that the actual
90:16 universe of adverse reports or complications is
90:17 certainly going to be higher than what is actually
90:18 reported?

03_21_18 combo final2_1-Altonaga 10-22-13 Booker Depo Designations Final2.1

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90:19 A. I have no idea. I have no idea how to answer
 90:20 that. I can only respond to if someone reports
 90:21 something that needs to be reported, it's reported. How
 90:22 many of those would not? I have no idea.

90:23 - 91:6

Altonaga, Bill 10-22-2013 (00:00:17)

03_21_18 combo final2_1.12

90:23 Q. Okay. But I think you told me a little while
 90:24 ago you agree that the MDR reporting system doesn't
 91:1 capture the universe of adverse events?

91:2 A. Yes.

91:3 Q. Does it then stand to reason that the actual
 91:4 number of adverse events is some percentage higher than
 91:5 what's actually reported?

91:6 A. I think that's reasonable.

91:13 - 91:16

Altonaga, Bill 10-22-2013 (00:00:14)

03_21_18 combo final2_1.13

91:13 Q. Sir, I'm going to back up for a second. I
 91:14 think you indicated when you started at Bard that was in
 91:15 2007?

91:16 A. 2008.

92:18 - 92:24

Altonaga, Bill 10-22-2013 (00:00:27)

03_21_18 combo final2_1.14

92:18 Q. All right. And what was your first exposure to
 92:19 IVC filters in your career?

92:20 A. My first exposure to IVC filters was at Bard.
 92:21 I don't remember exactly when, but it was when I was
 92:22 started working at Bard.

92:23 Q. In 2008?

92:24 A. Correct. It may have been after 2008.

125:22 - 126:1

Altonaga, Bill 10-22-2013 (00:00:12)

03_21_18 combo final2_1.15

125:22 Q. And if there is perforation of the filter
 125:23 outside of the vena cava into the aorta, that is likely
 125:24 a fatal event, is it not?

126:1 A. No, not necessarily.

126:9 - 126:16

Altonaga, Bill 10-22-2013 (00:00:26)

03_21_18 combo final2_1.16

126:9 Q. What would be your concerns?

126:10 A. My concerns would be that the presence of that
 126:11 limb, of whether it's affecting the aorta or not, I
 126:12 would certainly rely on images and experts, vascular
 126:13 interventionalists, to assess that case. And again,
 126:14 it's all about risk-benefit to that patient, but the
 126:15 mere fact that it's simply into the aorta doesn't mean
 126:16 that I think it's the highest severity of issues.

Page/Line	Source	ID
136:7 - 136:18	Altonaga, Bill 10-22-2013 (00:00:35) 136:7 Q. So you do acknowledge that one of 136:8 the problems with fracture can involve the embolization 136:9 of that fracture fragment to other parts of the body? 136:10 A. I am, yes. 136:11 Q. All right. And give us some idea as to the 136:12 organs and parts of the body that a fracture can 136:13 embolize to. 136:14 A. I would say that the most likely place for it 136:15 to fracture would be up through the vena cava into the 136:16 right atrium. Its resting location could be the right 136:17 atrium, it could go into the left ventricle, or it could 136:18 end up in pulmonary circulation.	03_21_18 combo final2_1.17
142:10 - 142:17	Altonaga, Bill 10-22-2013 (00:00:31) 142:10 Q. And as a medical doctor, do you acknowledge 142:11 that the vena cava can actually expand by as much up to 142:12 50 percent its resting size? 142:13 A. I believe that that's true. 142:14 Q. Okay. As an example, if an individual has a 142:15 28-millimeter vena cava, given the various dynamics, 142:16 that could actually expand up to 42 millimeters, agreed? 142:17 A. Agreed.	03_21_18 combo final2_1.18
149:16 - 150:1	Altonaga, Bill 10-22-2013 (00:00:27) 149:16 Q. All right. And -- so just simply to throw out 149:17 the idea that filters are known to migrate, perforate, 149:18 or fracture, that sort of begs the question, does it 149:19 not, because you have to have an understanding of the 149:20 rate at which that occurs in order to know whether your 149:21 complication rate is either acceptable or not 149:22 acceptable? 149:23 A. Okay. 149:24 Q. Do you agree? 150:1 A. I don't disagree with that.	03_21_18 combo final2_1.19
152:6 - 152:10	Altonaga, Bill 10-22-2013 (00:00:10) 152:6 Q. Bard's required to be 152:7 transparent and upfront with all information, whether 152:8 it's good or bad? 152:9 A. I would think that they're required to do so, 152:10 yes.	03_21_18 combo final2_1.20
152:16 - 152:20	Altonaga, Bill 10-22-2013 (00:00:18)	03_21_18 combo final2_1.21

Page/Line	Source	ID
	152:16 Q. Rate of complications, for example.	
	152:17 A. No, I don't -- I don't think that -- that is a	
	152:18 responsibility of a medical device company to provide	
	152:19 rates. If they're asked or solicited, we may provide	
	152:20 that.	
152:24 - 153:7	Altonaga, Bill 10-22-2013 (00:00:23)	03_21_18 combo final2_1.22
	152:24 Q. And what is a warning and what's the	
	153:1 purpose behind issuing a warning to a physician or	
	153:2 healthcare provider that is using a Bard device?	
	153:3 A. Just like the warnings that are provided in the	
	153:4 instructions for use of every medical device. It's	
	153:5 known or identified events that may put the patient at	
	153:6 risk, whether it's in the form of contraindication or	
	153:7 precaution or warning.	
153:17 - 153:20	Altonaga, Bill 10-22-2013 (00:00:08)	03_21_18 combo final2_1.23
	153:17 A. I don't know how to answer that. It depends on	
	153:18 the issue. It depends on the severity of harm. It	
	153:19 depends on a lot of different variables. So it's a very	
	153:20 open question. I don't know.	
157:19 - 158:4	Altonaga, Bill 10-22-2013 (00:00:25)	03_21_18 combo final2_1.24
	157:19 THE COURT REPORTER: "Would it be your	
	157:20 expectation that when Bard launches a filter for	
	157:21 commercial use that Bard would have an awareness	
	157:22 about the long-term clinical performance of that	
	157:23 device?"	
	157:24 A. Yes.	
	158:1 Q. Why? Why would that be important?	
	158:2 A. Because I think it's prudent for the medical	
	158:3 device company to understand how its device performs	
	158:4 regarding safety and effectiveness.	
158:5 - 158:6	Altonaga, Bill 10-22-2013 (00:00:06)	03_21_18 combo final2_1.25
	158:5 Q. And how would you expect Bard to develop that	
	158:6 awareness with its IVC filter?	
158:10 - 158:12	Altonaga, Bill 10-22-2013 (00:00:06)	03_21_18 combo final2_1.26
	158:10 A. Based on postmarket surveillance, based on	
	158:11 literature, based on clinical trials, a lot of different	
	158:12 ways.	
160:8 - 160:8	Altonaga, Bill 10-22-2013 (00:00:01)	03_21_18 combo final2_1.27
	160:8 Q. Sir, have you ever seen that e-mail before?	
160:11 - 160:22	Altonaga, Bill 10-22-2013 (00:00:20)	03_21_18 combo final2_1.28

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	160:11 A. No, I've never seen this e-mail before.	
	160:12 Q. Do you know the individuals that are a part of	
	160:13 that e-mail string?	
	160:14 A. No, I do not.	
	160:15 Q. You don't know who Janet Hudnall is?	
	160:16 A. No, I don't.	
	160:17 Q. David Rauch, R-a-u-c-h?	
	160:18 A. I think I've heard the name. I've never met	
	160:19 that person, I don't believe.	
	160:20 Q. Do you have any idea what his position is at	
	160:21 Bard?	
	160:22 A. No, sir.	
166:16 - 166:24	Altonaga, Bill 10-22-2013 (00:00:38)	03_21_18 combo final2_1.29
	166:16 Q. All right. And then at the top, Dave Rauch	
	166:17 replies to Janet Hudnall and says: "Thank you for your	
	166:18 valuable feedback. You are right. Now that we have	
	166:19 more experience with Recovery, the positioning of tilt	
	166:20 resistance should probably be downplayed."	
	166:21 Now, does that bother you that, based on the	
	166:22 information as of February 27th, 2004, there are	
	166:23 communications from one person to another about	
	166:24 downplaying the issues relating to tilt resistance?	
167:3 - 167:7	Altonaga, Bill 10-22-2013 (00:00:17)	03_21_18 combo final2_1.30
	167:3 A. Yeah. I don't know what thought process was	
	167:4 behind Dave Rauch's answer.	
	167:5 Q. Well, if somebody is suggesting that Bard not	
	167:6 provide the full picture regarding positioning of tilt	
	167:7 resistance, does that bother you?	
167:9 - 167:9	Altonaga, Bill 10-22-2013 (00:00:03)	03_21_18 combo final2_1.31
	167:9 A. In general, yeah, that's a concern.	
168:5 - 168:9	Altonaga, Bill 10-22-2013 (00:00:15)	03_21_18 combo final2_1.32
	168:5 Q. Well, you're a medical doctor, and do you at	
	168:6 least acknowledge that the more information a clinical	
	168:7 physician has, the better he or she can make decisions	
	168:8 about what medical device to use in a particular	
	168:9 patient?	
168:12 - 168:13	Altonaga, Bill 10-22-2013 (00:00:02)	03_21_18 combo final2_1.33
	168:12 A. In very general terms, I don't disagree with	
	168:13 that.	
169:8 - 169:20	Altonaga, Bill 10-22-2013 (00:00:42)	03_21_18 combo final2_1.34

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	169:8 Q. And if there is instability with respect to 169:9 centering or tilt, do you acknowledge that can have 169:10 harmful effects on a patient? 169:11 A. There can be varying degrees of effect due to 169:12 tilt of a filter. 169:13 Q. Some of which can be significant? 169:14 A. Some of which can be. 169:15 Q. And when I say significant, I'm talking about 169:16 can pose significant health risks to the patient. 169:17 A. Could affect the performance of the filter. 169:18 Q. That can in turn have significant -- pose 169:19 significant health risk to the patient. Agreed? 169:20 A. I can agree with that statement.	
170:7 - 170:10	Altonaga, Bill 10-22-2013 (00:00:13) 170:7 Q. And if that happened, again, drawing on your 170:8 education and your background and experience in the 170:9 field of medical affairs, do you acknowledge that would 170:10 be inappropriate?	03_21_18 combo final2_1.35
170:12 - 170:13	Altonaga, Bill 10-22-2013 (00:00:03) 170:12 A. As I said before, under that context, I would 170:13 agree with that statement.	03_21_18 combo final2_1.36
171:10 - 171:10	Altonaga, Bill 10-22-2013 (00:00:02) 171:10 MR. JOHNSON: Let's mark that as Exhibit 4.	03_21_18 combo final2_1.37
172:12 - 172:14	Altonaga, Bill 10-22-2013 (00:00:04) 172:12 Q. All right. Have you ever seen that string of 172:13 e-mails prior to today? 172:14 A. No, sir.	03_21_18 combo final2_1.38
179:20 - 180:7	Altonaga, Bill 10-22-2013 (00:01:06) 179:20 Q. Sir, going back to Exhibit 4, the statement 179:21 that this, referring to migration, is true for all 179:22 filters, if the message going forward on the part of 179:23 Bard was that there was no significant difference in the 179:24 rates of complications between the Recovery filter and 180:1 any of the other devices currently marketed in the U.S., 180:2 if that -- if there was evidence that Bard knew 180:3 otherwise, that that statement was not true, would that 180:4 be an example of misbranding? 180:5 A. I would -- I would have to say that it could be 180:6 looked upon as misrepresentation or misbranding or 180:7 misleading if that, in fact, is true.	03_21_18 combo final2_1.39

03_21_18 combo final2_1-Altonaga 10-22-13 Booker Depo Designations Final2.1

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180:11 - 180:11	Altonaga, Bill 10-22-2013 (00:00:01)	03_21_18 combo final2_1.40
	180:11 Exhibit 5	
180:21 - 180:22	Altonaga, Bill 10-22-2013 (00:00:02)	03_21_18 combo final2_1.41
	180:21 Q. Have you ever seen that document?	
	180:22 A. No, sir.	
182:4 - 182:6	Altonaga, Bill 10-22-2013 (00:00:05)	03_21_18 combo final2_1.42
	182:4 Q. And for the record, this document is dated	
	182:5 August 30th of 2004, is it not?	
	182:6 A. It is.	
182:19 - 183:3	Altonaga, Bill 10-22-2013 (00:00:36)	03_21_18 combo final2_1.43
	182:19 Q. All right. And even though this document was	
	182:20 not supposed to be given to third parties -- it's an	
	182:21 internal document -- if a spokesperson for Bard publicly	
	182:22 said or said this to a physician or to a hospital or	
	182:23 anybody making inquiry that estimates based on available	
	182:24 data suggests that these types of events are not	
	183:1 occurring with excess frequency when compared with other	
	183:2 competitive products, if that was false or misleading,	
	183:3 would that be another example of misbranding?	
183:5 - 183:24	Altonaga, Bill 10-22-2013 (00:01:33)	03_21_18 combo final2_1.44
	183:5 A. If that were true, I would say yes.	
	183:6 Q. Okay. And I haven't asked you this, but why	
	183:7 aren't companies supposed to misbrand? What's the harm?	
	183:8 A. You mean to knowingly mislead the public?	
	183:9 Q. Or doctors that are using --	
	183:10 A. Or doctors, right.	
	183:11 Q. Yes. What's the harm? Why do you not want to	
	183:12 do it? When I say not want to do it, why do you -- why	
	183:13 is it improper to misbrand in a practical everyday	
	183:14 sense? What's the public safety element to that?	
	183:15 A. Because by misleading the public, you're not	
	183:16 making them aware of all the risks associated with a	
	183:17 particular issue.	
	183:18 Q. Okay. For example, with migration, by telling	
	183:19 physicians for example, that implant the IVC filter,	
	183:20 that the available data suggests that migration does not	
	183:21 occur with excess frequency when compared with other	
	183:22 competitive products, would you agree that that could be	
	183:23 influential in decision-making on the part of a doctor	
	183:24 in choosing a particular IVC filter?	

03_21_18 combo final2_1-Altonaga 10-22-13 Booker Depo Designations Final2.1

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184:2 - 184:2	Altonaga, Bill 10-22-2013 (00:00:01)	03_21_18 combo final2_1.45
	184:2 A. I could interpret it to be that, yes.	
216:11 - 216:21	Altonaga, Bill 10-22-2013 (00:00:31)	03_21_18 combo final2_1.46
	216:11 A. But all these	
	216:12 data are based on, it appears to be, MAUDE database. So	
	216:13 that means that that's only what was reported, not	
	216:14 actually what occurred.	
	216:15 Q. What do you mean by that?	
	216:16 A. Meaning that it's only -- that numerator will	
	216:17 only come if that information is reported, so -- or	
	216:18 published by the FDA on their website. So, I guess,	
	216:19 again, I'm just trying to show that there could be some	
	216:20 statistical method issues here with how you're comparing	
	216:21 these data.	
243:16 - 243:18	Altonaga, Bill 10-22-2013 (00:00:08)	03_21_18 combo final2_1.47
	243:16 Don't you think that the	
	243:17 doctors who are implanting these devices should be aware	
	243:18 of these significant differences in the safety profile?	
243:20 - 243:21	Altonaga, Bill 10-22-2013 (00:00:06)	03_21_18 combo final2_1.48
	243:20 A. I think that the doctors should be aware of the	
	243:21 rates of complications associated with these devices. I	
251:3 - 251:6	Altonaga, Bill 10-22-2013 (00:00:08)	03_21_18 combo final2_1.49
	251:3 Q. Did Bard, to your knowledge, ever sponsor a	
	251:4 randomized clinical trial to assess the safety of the	
	251:5 Recovery Filter?	
	251:6 A. That I'm aware of, no.	
261:1 - 261:3	Altonaga, Bill 10-22-2013 (00:00:03)	03_21_18 combo final2_1.50
	261:1 Q. First of all, have you ever seen this health	
	261:2 hazard evaluation prior?	
	261:3 A. No, I believe not.	
266:1 - 266:12	Altonaga, Bill 10-22-2013 (00:00:40)	03_21_18 combo final2_1.51
	266:1 A. I think that, you know, we're talking about	
	266:2 something that was nine years ago, right? So you're	
	266:3 asking me a question based on what at that time may have	
	266:4 constituted an ethical approach to conducting a	
	266:5 randomized trial. A randomized trial means that at the	
	266:6 time the patient presents, they're going to pull out an	
	266:7 envelope and decide whether they get a filter or not,	
	266:8 for instance. And there may be some medical --	
	266:9 legal-medical ethical issues associated with that	

03_21_18 combo final2_1-Altonaga 10-22-13 Booker Depo Designations Final2.1

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266:10 practice. So when it involves a device that has
266:11 mortality associated with it, one has to consider that,
266:12 so that would be one challenge associated with a trial.

Plaintiffs Designations = 00:13:20

Defense Designations = 00:04:27

Their Conditionals = 00:00:18

Total Time = 00:18:05

EXHIBIT L

Designation Run Report

Ferrara 04-07-17 Booker Depo Designations Final3

Ferrara, Robert 04-07-2017

Plaintiffs Designations 00:11:10

Plaintiffs Counters 00:00:49

Defense Designations 00:06:31

Total Time 00:18:30



03_21_18 combo final3-Ferrara 04-07-17 Booker Depo Designations Final3

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12:5 - 12:7	Ferrara, Robert 04-07-2017 (00:00:02) 12:5 Q. please just state your 12:6 name for the record? 12:7 A. Sure. Robert Ferrara.	03_21_18 combo final3.1
100:7 - 100:8	Ferrara, Robert 04-07-2017 (00:00:03) 100:7 Q. Mr. Ferrara, let me show you 100:8 Exhibit Number 3.	03_21_18 combo final3.4
101:14 - 101:23	Ferrara, Robert 04-07-2017 (00:00:32) 101:14 Q. And what is that document, or 101:15 what does it appear to be? 101:16 A. It appears to be an e-mail from 101:17 Regina to myself, Regina my manager I'm 101:18 assuming at the time. I guess -- I don't 101:19 remember this specific document, but it 101:20 looks like it was some time that she rode 101:21 with me in the field and it looks like a 101:22 snapshot of her feelings and follow-up on 101:23 it.	03_21_18 combo final3.5
103:16 - 103:23	Ferrara, Robert 04-07-2017 (00:00:23) 103:16 Q. Did she, or tell us 103:17 what she said in there about the doctor 103:18 seeing you as a trusted advisor. 103:19 A. "You have done an excellent job 103:20 in building a strong relationship with 103:21 everybody in IR. Your role there is not 103:22 sales -- a salesperson. You are seen as a 103:23 trusted advisor."	03_21_18 combo final3.8
104:12 - 104:24	Ferrara, Robert 04-07-2017 (00:00:30) 104:12 Q. Did you consider yourself a 104:13 trusted advisor to the physicians? 104:14 *** 104:15 *** 104:16 A. I considered myself a help in 104:17 any way I could be. 104:18 Q. Can you keep reading the 104:19 highlighted portion, please? 104:20 A. "The radiologists and support 104:21 staff look to you for clinical knowledge." 104:22 Q. Do you agree with that 104:23 statement?	03_21_18 combo final3.12

03_21_18 combo final3-Ferrara 04-07-17 Booker Depo Designations Final3

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105:6 - 105:9	<p>104:24 A. At times, sure.</p> <p>Ferrara, Robert 04-07-2017 (00:00:04)</p> <p>105:6 Q. Please read the</p> <p>105:7 portion that's highlighted under "Clinical</p> <p>105:8 knowledge."</p> <p>105:9 A. Okay.</p>	03_21_18 combo final3.13
105:18 - 106:5	<p>Ferrara, Robert 04-07-2017 (00:00:25)</p> <p>105:18 So, the highlighted portion</p> <p>105:19 reads: "Prior to the retrieval at RWJ in</p> <p>105:20 the open New Jersey territory, you did a</p> <p>105:21 good job detailing the difference between</p> <p>105:22 the Recovery and the G2. You know the</p> <p>105:23 features and benefits, as well as recent</p> <p>105:24 literature regarding the performance of</p> <p>106:1 the filters. The doctor was impressed</p> <p>106:2 that you knew what article he was</p> <p>106:3 referring to on migration and was able to</p> <p>106:4 share with you -- share your thoughts with</p> <p>106:5 him."</p>	03_21_18 combo final3.14
111:6 - 111:22	<p>Ferrara, Robert 04-07-2017 (00:00:43)</p> <p>111:6 Q. Would you agree or</p> <p>111:7 disagree that the clinical knowledge that</p> <p>111:8 you would be giving your clients would be</p> <p>111:9 knowledge of a product's strengths and</p> <p>111:10 weaknesses?</p> <p>111:11 A. Potentially.</p> <p>111:12 Q. Would you agree that a primary</p> <p>111:13 concern of Bard in developing and selling</p> <p>111:14 medical products need to be the safety of</p> <p>111:15 the patient?</p> <p>111:16 A. Sure, I think it's reasonable.</p> <p>111:17 Q. And would you agree that doctors</p> <p>111:18 need to be able to trust you in giving</p> <p>111:19 them information that's reliable and</p> <p>111:20 trustworthy about the products?</p> <p>111:21 A. I -- I believe that we have to</p> <p>111:22 give them accurate information.</p>	03_21_18 combo final3.15
111:23 - 112:2	<p>Ferrara, Robert 04-07-2017 (00:00:09)</p> <p>111:23 Q. Do you believe that that</p> <p>111:24 information needs to be updated on a</p>	03_21_18 combo final3.16

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112:5 - 112:12	<p>112:1 regular and ongoing basis when the</p> <p>112:2 information changes over time?</p> <p>Ferrara, Robert 04-07-2017 (00:00:21)</p> <p>112:5 A. I don't know if I necessarily</p> <p>112:6 agree with that from the standpoint of</p> <p>112:7 what re -- so, what actually require --</p> <p>112:8 requires dissemination of new information,</p> <p>112:9 what is new information, what is -- what</p> <p>112:10 does Bard deem necessary, because there --</p> <p>112:11 there's new information about everything</p> <p>112:12 all the day -- every day.</p>	03_21_18 combo final3.17
113:7 - 114:2	<p>Ferrara, Robert 04-07-2017 (00:00:41)</p> <p>113:7 Q. All right. But if you learn</p> <p>113:8 information that would potentially affect</p> <p>113:9 a doctor's decision about whether to</p> <p>113:10 implant a product and it's not on this</p> <p>113:11 approved dissemination list, do you feel a</p> <p>113:12 responsibility to tell the doctor that</p> <p>113:13 information?</p> <p>113:14 A. Whatever -- whatever -- any</p> <p>113:15 information that's unapproved for me to</p> <p>113:16 disseminate to a physician I will not</p> <p>113:17 disseminate to a physician.</p> <p>113:18 Q. So you're relying on Bard to</p> <p>113:19 give you the go-ahead on disseminating any</p> <p>113:20 information?</p> <p>113:21 A. On -- on -- on approved</p> <p>113:22 information, yeah.</p> <p>113:23 Q. All right. So if it wasn't</p> <p>113:24 approved by Bard, you weren't</p> <p>114:1 disseminating it?</p> <p>114:2 A. As far as I know.</p>	03_21_18 combo final3.18
116:9 - 116:16	<p>Ferrara, Robert 04-07-2017 (00:00:15)</p> <p>116:9 Q. Do you agree or disagree that</p> <p>116:10 marketing materials put out by a</p> <p>116:11 manufacturer, in this situation Bard, I'll</p> <p>116:12 break it down, should be truthful?</p> <p>116:13 A. Yes.</p> <p>116:14 Q. Should the marketing materials</p> <p>116:15 put out by Bard be accurate?</p>	03_21_18 combo final3.19

03_21_18 combo final3-Ferrara 04-07-17 Booker Depo Designations Final3

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116:17 - 116:19	<p>116:16 A. Yes.</p> <p>Ferrara, Robert 04-07-2017 (00:00:06)</p> <p>116:17 Q. Should the marketing materials</p> <p>116:18 put out by Bard contain all pertinent</p> <p>116:19 information for a doctor?</p>	03_21_18 combo final3.20
116:22 - 116:24	<p>Ferrara, Robert 04-07-2017 (00:00:07)</p> <p>116:22 A. As defined by what Bard has</p> <p>116:23 approved and data for and can back up,</p> <p>116:24 claims that they can back up.</p>	03_21_18 combo final3.21
117:1 - 117:9	<p>Ferrara, Robert 04-07-2017 (00:00:22)</p> <p>117:1 Q. So you think that's up to Bard</p> <p>117:2 to decide what's pertinent?</p> <p>117:3 A. I think that anything put in a</p> <p>117:4 Bard piece of literature has to be</p> <p>117:5 approved by Bard legal and internal</p> <p>117:6 processes.</p> <p>117:7 Q. Okay.</p> <p>117:8 A. And I don't know anything about</p> <p>117:9 those processes and have no input on them.</p>	03_21_18 combo final3.22
121:1 - 121:5	<p>Ferrara, Robert 04-07-2017 (00:00:17)</p> <p>121:1 Q. When you first started selling</p> <p>121:2 the IVC filters, even on a limited basis,</p> <p>121:3 what was your understanding about any</p> <p>121:4 testing that had been done for the safety</p> <p>121:5 of the -- let's start with the Simon?</p>	03_21_18 combo final3.23
121:9 - 122:7	<p>Ferrara, Robert 04-07-2017 (00:00:59)</p> <p>121:9 A. I don't -- I don't really have</p> <p>121:10 any knowledge of any of the testing.</p> <p>121:11 Q. All right. Do you have any</p> <p>121:12 knowledge whatsoever of the testing done</p> <p>121:13 by Bard for the safety or effectiveness of</p> <p>121:14 the Recovery filter?</p> <p>121:15 A. No.</p> <p>121:16 Q. Did Bard, in your training</p> <p>121:17 session in Arizona, discuss any sort of</p> <p>121:18 testing that you recall?</p> <p>121:19 A. Not that I recall.</p> <p>121:20 Q. Do you think a doctor would</p> <p>121:21 expect that testing had been done on a</p> <p>121:22 product for its safety and effectiveness</p>	03_21_18 combo final3.24

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	121:23 prior to it being released into the 121:24 market? 122:1 A. I think as a general assumption, 122:2 physicians would expect that products are 122:3 tested before they're released to the 122:4 market. 122:5 Q. Would you agree or disagree that 122:6 it is a good idea to hide data or studies 122:7 from a doctor on a product?	
122:10 - 122:11	Ferrara, Robert 04-07-2017 (00:00:06)	03_21_18 combo final3.25
	122:10 A. I don't think that it is a good 122:11 idea to -- to do that.	
124:22 - 125:6	Ferrara, Robert 04-07-2017 (00:00:26)	03_21_18 combo final3.27
	124:22 Q. Would you do that in writing in 124:23 addition to calling or e-mailing, like a 124:24 report I mean? 125:1 A. I -- no. I think that all we 125:2 did was relay the facts -- we had to relay 125:3 the facts of the event, and I believe I 125:4 did that via phone. I don't know if we 125:5 ever did it via e-mail, but that was 125:6 essentially the process.	
131:11 - 131:19	Ferrara, Robert 04-07-2017 (00:00:24)	03_21_18 combo final3.28
	131:11 Q. And do you know whether Bard 131:12 tracked the issues, problems, concerns, 131:13 failures that arose with the filters? 131:14 A. I don't really know what they 131:15 did with the data. I know they had to 131:16 capture it all. 131:17 Q. Did they ever provide you as a 131:18 sales rep with any of that information? 131:19 A. Not that I recall.	
133:15 - 135:5	Ferrara, Robert 04-07-2017 (00:02:10)	03_21_18 combo final3.29
	133:15 Q. Did you have an understanding at 133:16 that point when you first started working 133:17 there, after your training of course, of 133:18 the difference between the Simon and the 133:19 Recovery? 133:20 A. Again, being newer, I knew some 133:21 differences in the broad strokes.	

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133:22 Q. And what was the basic
 133:23 difference between the two?
 133:24 A. So, the -- if memory serves
 134:1 correct, the Simon Nitinol had a femoral,
 134:2 a jugular and an antecubital. The
 134:3 Recovery had a femoral in terms of a
 134:4 access site kit. The Recovery was
 134:5 retrievable. The Simon Nitinol -- the
 134:6 Recovery was permanent or retrievable.
 134:7 The Simon Nitinol was permanent only.
 134:8 The general feedback was that
 134:9 physicians preferred the Recovery, then
 134:10 the Simon Nitinol. The Simon Nitinol was
 134:11 a very good filter. It was the -- I
 134:12 believe it was the first low profile
 134:13 filter that was out, and a lot of people
 134:14 had experience with that.
 134:15 The big kind of discrepancy
 134:16 between the two was when the Simon Nitinol
 134:17 was introduced into the patient for
 134:18 deployment, they -- it appeared -- it was
 134:19 pack -- it was compressed on the wire or
 134:20 packaged and it was very long, and then
 134:21 when you actually deployed it in the
 134:22 patient, there was a foreshortening of the
 134:23 device and it would make it -- it would
 134:24 make it not a direct one-to-one
 135:1 positioning of where you would end up with
 135:2 it, and physicians preferred, for the most
 135:3 part, the Recovery that where it sat is
 135:4 pretty much where it was deployed. So
 135:5 those were some of the big differences.

137:19 - 138:2

Ferrara, Robert 04-07-2017 (00:00:29)

03_21_18 combo final3.30

137:19 Q. What does the term "tilt" mean?
 137:20 A. So, I believe the term "tilt," I
 137:21 assume you are saying with respect to
 137:22 filters, is that if in a perfect world in
 137:23 a perfect cava in a perfect tube it would
 137:24 sit perpendicular to the cava wall, that a
 138:1 tilt would indicate that it was not

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138:5 - 138:15	<p>138:2 perpendicular to the cava wall.</p> <p>Ferrara, Robert 04-07-2017 (00:00:32)</p> <p>138:5 Is it supposed to be straight up</p> <p>138:6 and down; it's supposed to be --</p> <p>138:7 A. Well, it's hard to really --</p> <p>138:8 it's hard to really talk -- you could talk</p> <p>138:9 in ideal terms. In I -- in a perfectly</p> <p>138:10 ideal world, which God does not tend to</p> <p>138:11 create in our bodies, from my experience,</p> <p>138:12 the cava would be a perfectly straight up</p> <p>138:13 and down, totally concentric tube, and the</p> <p>138:14 filter would sit straight up and down,</p> <p>138:15 totally concentric in that tube.</p>	03_21_18 combo final3.31
142:15 - 142:19	<p>Ferrara, Robert 04-07-2017 (00:00:11)</p> <p>142:15 Q. The question is is tilt,</p> <p>142:16 migration, fracture and perforation a good</p> <p>142:17 thing?</p> <p>142:18 A. Tilt, migration, fracture and</p> <p>142:19 perforation are not a good thing.</p>	03_21_18 combo final3.37
143:3 - 143:6	<p>Ferrara, Robert 04-07-2017 (00:00:04)</p> <p>143:3 Q. Can they be hazardous to a</p> <p>143:4 patient's health?</p> <p>143:5 A. They can be benign or hazardous</p> <p>143:6 to a patient's health.</p>	03_21_18 combo final3.38
204:18 - 204:22	<p>Ferrara, Robert 04-07-2017 (00:00:09)</p> <p>204:18 Were you ever given any</p> <p>204:19 information about any differences between</p> <p>204:20 the Recovery fracture rates and any other</p> <p>204:21 IVC filter?</p> <p>204:22 A. No.</p>	03_21_18 combo final3.42
225:22 - 226:4	<p>Ferrara, Robert 04-07-2017 (00:00:15)</p> <p>225:22 Q. And was it being marketed</p> <p>225:23 as having reduced tilt?</p> <p>225:24 A. Sure.</p> <p>226:1 Q. Was it being marketed as</p> <p>226:2 increased fracture resistance, as having</p> <p>226:3 increased fracture resistance?</p> <p>226:4 A. Sure.</p>	03_21_18 combo final3.43
226:5 - 226:5	<p>Ferrara, Robert 04-07-2017 (00:00:08)</p> <p>226:5 Enhanced fracture resistance.</p>	03_21_18 combo final3.44

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226:22 - 227:5	Ferrara, Robert 04-07-2017 (00:00:16) 226:22 Q. Okay. Because at this time when 226:23 the G2 filter came out, the Simon was 226:24 still available? 227:1 A. The Simon Nitinol filter. Yeah, 227:2 the Simon Nitinol filter, I believe, was 227:3 still available. A lot of physicians 227:4 didn't use it. So I maybe had a -- a 227:5 couple of guys who ordered it.	03_21_18 combo final3.45
231:3 - 231:7	Ferrara, Robert 04-07-2017 (00:00:16) 231:3 Q. Please take a look 231:4 at Exhibit 19, which is an e-mail from 231:5 David Ciavarella to Brian Barry. That 231:6 e-mail's dated December 27th of 2005. 231:7 A. Okay.	03_21_18 combo final3.46
231:22 - 232:1	Ferrara, Robert 04-07-2017 (00:00:08) 231:22 Q. This e-mail chain 231:23 has to do with caudal migrations of the 231:24 G2; is that right? 232:1 A. It appears to, yeah.	03_21_18 combo final3.47
232:10 - 233:5	Ferrara, Robert 04-07-2017 (00:00:59) 232:10 Q. Do you see that David Ciavarella 232:11 says that: "The G2 is a permanent filter 232:12 and we also have one, the Simon Nitinol, 232:13 that has virtually no complaints 232:14 associated with it. Why shouldn't doctors 232:15 be using that one rather than the G2?" 232:16 A. Okay. 232:17 Q. Okay. Did you know as of 232:18 December 2005 that there were concerns 232:19 about caudal migration with the G2? 232:20 A. So, I knew that there were 232:21 incidents of caudal migrations with the 232:22 G2. I can't give you a specific time 232:23 frame that I was aware of them. 232:24 Q. Okay. Do you recall ever 233:1 discussing the caudal migration issue with 233:2 your physicians that you were seeing? 233:3 A. I can't -- we may have discussed 233:4 it. I can't recall a specific incidence	03_21_18 combo final3.48

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233:12 - 233:17	<p>233:5 of discussing.</p> <p>Ferrara, Robert 04-07-2017 (00:00:12)</p> <p>233:12 Q. Did you ever talk to Dr.</p> <p>233:13 D'Ayala --</p> <p>233:14 A. D'Ayala.</p> <p>233:15 Q. D'Ayala about caudal migration</p> <p>233:16 with the G2?</p> <p>233:17 A. I couldn't say specifically.</p>	03_21_18 combo final3.49
249:17 - 249:19	<p>Ferrara, Robert 04-07-2017 (00:00:07)</p> <p>249:17 Q. Were you aware while you were</p> <p>249:18 working at Bard that the G2 had more</p> <p>249:19 caudal migrations than the Recovery?</p>	03_21_18 combo final3.50
249:22 - 250:8	<p>Ferrara, Robert 04-07-2017 (00:00:24)</p> <p>249:22 A. I wasn't privy to the numbers</p> <p>249:23 for both of them. So I wouldn't be privy</p> <p>249:24 to any of that.</p> <p>250:1 Q. So, the same would be true about</p> <p>250:2 the more tilting and more perforations?</p> <p>250:3 A. Any tilting or any perforation</p> <p>250:4 rate I would not have specific access to.</p> <p>250:5 Q. All right. So I would take it</p> <p>250:6 from this answer you would have not been</p> <p>250:7 able to relay that information to Dr.</p> <p>250:8 D'Ayala?</p>	03_21_18 combo final3.51
250:15 - 250:17	<p>Ferrara, Robert 04-07-2017 (00:00:05)</p> <p>250:15 A. I could not have passed</p> <p>250:16 to Dr. D'Ayala any information that I</p> <p>250:17 didn't have or was approved to give him.</p>	03_21_18 combo final3.52
250:22 - 251:21	<p>Ferrara, Robert 04-07-2017 (00:00:52)</p> <p>250:22 Q. Have you ever heard of the</p> <p>250:23 migration push test?</p> <p>250:24 A. No.</p> <p>251:1 Q. Are you aware of any kind of</p> <p>251:2 test done by Bard to determine how much</p> <p>251:3 force any of its filters could endure</p> <p>251:4 before they migrated?</p> <p>251:5 A. Anecdotally I may have heard</p> <p>251:6 that they did some type of testing, but I</p> <p>251:7 couldn't tell you any specifics.</p> <p>251:8 Q. Were you ever given any</p>	03_21_18 combo final3.53

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	251:9 information from that study that compared 251:10 the G2 to any other filters? 251:11 A. Which study? 251:12 Q. The migration push test? 251:13 A. No, I was not given any 251:14 information from any test. 251:15 Q. So again, if you didn't have 251:16 that information, you would not be able to 251:17 provide that information to any of the 251:18 physicians that you worked with? 251:19 A. Correct, I could not provide any 251:20 information I did not have or was approved 251:21 to give.	
283:8 - 283:13	Ferrara, Robert 04-07-2017 (00:00:17) 283:8 Q. All right. So, in terms of any 283:9 studies that Bard did comparing their 283:10 filter, either the Recovery or the G2, to 283:11 other filters, you don't think that they 283:12 had to -- the responsibility to share that 283:13 information?	03_21_18 combo final3.54
283:16 - 283:19	Ferrara, Robert 04-07-2017 (00:00:07) 283:16 A. I don't feel they had the 283:17 responsibility to share any information 283:18 that's not level 1A evidence, like a true 283:19 clinical trial.	03_21_18 combo final3.55
284:12 - 284:16	Ferrara, Robert 04-07-2017 (00:00:18) 284:12 Q. do you think it's being 284:13 honest not to tell her physician that the 284:14 filter that's about to be implanted into 284:15 her body has a greater propensity to tilt, 284:16 migrate, or penetrate than other filters?	03_21_18 combo final3.56
284:22 - 285:7	Ferrara, Robert 04-07-2017 (00:00:33) 284:22 I think that Dr. D'Ayala 284:23 specifically was made aware of the 284:24 potential complications of the IVC filter 285:1 and all IVC filters. You're describing 285:2 complications, known complications of an 285:3 IVC filter, and I don't believe there is 285:4 any level 1A evidence about any type of 285:5 comparison between that filter and any	03_21_18 combo final3.57

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291:2 - 291:14	<p>285:6 other filter that would be appropriate and 285:7 approved to share with anyone.</p> <p>Ferrara, Robert 04-07-2017 (00:00:40)</p> <p>291:2 Q. Dr. D'Ayala has 291:3 testified that he would have liked to have 291:4 the information that was available about 291:5 the G2 filter, that it was more likely to 291:6 caudally migrate, more likely to tilt, 291:7 more likely to perforate. He would have 291:8 liked to have had that information before 291:9 he implanted any filter into Ms. Booker. 291:10 Do you have any reason that he 291:11 would not have been entitled to that 291:12 information other than your -- what you've 291:13 testified to, that it wasn't clinical 291:14 testing?</p>	03_21_18 combo final3.59
291:17 - 291:24	<p>Ferrara, Robert 04-07-2017 (00:00:15)</p> <p>291:17 A. I feel that if Dr. D'Ayala 291:18 wanted specific information and had 291:19 requested it from the company, the company 291:20 should do the best they can to comply with 291:21 his request. 291:22 Q. Well, you can't request 291:23 information that you don't know exists, 291:24 right?</p>	03_21_18 combo final3.60
292:3 - 292:10	<p>Ferrara, Robert 04-07-2017 (00:00:19)</p> <p>292:3 A. I don't know because I don't 292:4 know what exists either. 292:5 Q. Well, I mean, if he were sitting 292:6 there implanting these G2 filters and he 292:7 did not know that they were tilting and 292:8 perforating on a higher rate than other 292:9 filters, how would he know to ask that 292:10 question?</p>	03_21_18 combo final3.61
292:13 - 293:1	<p>Ferrara, Robert 04-07-2017 (00:00:31)</p> <p>292:13 A. So, I don't know -- so, when you 292:14 say that -- when you say tilting and 292:15 migration and that, those are all known 292:16 complications. 292:17 In terms of higher and not</p>	03_21_18 combo final3.62

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	292:18 higher, I cannot speak to you because I do 292:19 not know that to be fact. 292:20 So, what he would like to have 292:21 is, you know, his want, and the company 292:22 should do the best they can with that 292:23 want, but I cannot comment on what they 292:24 should have, would have, could have done 293:1 had he requested specific information.	
307:19 - 308:8	Ferrara, Robert 04-07-2017 (00:00:25) 307:19 Q. I think it's safe to say that 307:20 plaintiff's counsel has suggested that 307:21 Bard hid information from doctors 307:22 regarding IVC filters. 307:23 Is that characterization 307:24 consistent with your experience at Bard? 308:1 A. No. 308:2 Q. Did you ever feel pressured by 308:3 anyone at Bard to hide information from 308:4 physicians about Bard filters? 308:5 A. No. 308:6 Q. Did anyone at Bard ever ask you 308:7 to downplay risks with Bard filters? 308:8 A. No.	03_21_18 combo final3.71
308:24 - 309:4	Ferrara, Robert 04-07-2017 (00:00:10) 308:24 Q. In your experience, last 16 309:1 years experience in pharmaceutical or 309:2 medical device industry working with 309:3 doctors, what type of data do physicians 309:4 want to be provided?	03_21_18 combo final3.72
309:7 - 309:9	Ferrara, Robert 04-07-2017 (00:00:08) 309:7 A. So, again, each physician being 309:8 different, in my experience, they want 309:9 level 1A evidence data	03_21_18 combo final3.73
309:11 - 309:14	Ferrara, Robert 04-07-2017 (00:00:06) 309:11 Q. Do you have any reason to 309:12 believe that Bard withheld level 1 data 309:13 from you? 309:14 A. No.	03_21_18 combo final3.74

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Plaintiffs Designations = 00:11:10

Plaintiffs Counters = 00:00:49

Defense Designations = 00:06:31

Total Time = 00:18:30

EXHIBIT M

Designation Run Report

Greer 08-11-14 Booker Depo Designations Final

Greer, Jason 08-11-2014

Plaintiffs Designations 00:02:16

Defense Designations 00:02:26

Total Time 00:04:42



03_21_18 combo-Greer 08-11-14 Booker Depo Designations Final

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22:12 - 22:16	Greer, Jason 08-11-2014 (00:00:15) 22:12 Q. And was that the Lone Star territory? 22:13 A. No. That was my region when I was a regional sales 22:14 manager. My territory when I had it was Memphis. It didn't 22:15 really have a territory name. It may have been called Memphis. 22:16 I don't know.	03_21_18 combo.3
23:23 - 24:7	Greer, Jason 08-11-2014 (00:00:21) 23:23 Q. While you were a district manager, your 23:24 district was called the Lone Star State district, though, 23:25 right? 24:1 A. Yes. 24:2 Q. Okay. 24:3 A. Well, I believe it was -- yeah. I can't remember if 24:4 it was a period when I had Texas and part of Tennessee where we 24:5 weren't Lone Star, and then there was a period when I just had 24:6 Memphis and Texas, but I think it's all semantics. I had 24:7 Texas.	03_21_18 combo.5
59:22 - 59:24	Greer, Jason 08-11-2014 (00:00:08) 59:22 Q. Now, were you ever made aware that according to 59:23 Bard's own policy and procedure, the Recovery filter had an 59:24 unacceptable risk level and required product correction?	03_21_18 combo.6
60:1 - 60:5	Greer, Jason 08-11-2014 (00:00:22) 60:1 A. I was aware that, as with every product I've ever 60:2 sold, that there are opportunities to develop and improve the 60:3 product, especially when the rates are more in the median of 60:4 accepted rates, that you work to improve them, and there's 60:5 constantly engineers working on improving current products.	03_21_18 combo.7
60:6 - 60:9	Greer, Jason 08-11-2014 (00:00:06) 60:6 Q. When you were at 60:7 Bard, were you ever made aware that the Recovery filter 60:8 according to Bard's own policy and procedure had an 60:9 unacceptable risk level?	03_21_18 combo.8
60:11 - 60:13	Greer, Jason 08-11-2014 (00:00:12) 60:11 A. There was -- there was -- the question was raised by 60:12 sales people when I was a sales manager, and the response of 60:13 the company was always that the rates were acceptable.	03_21_18 combo.9
115:12 - 115:18	Greer, Jason 08-11-2014 (00:00:28) 115:12 it's -- it's in defense, in the defensive position. I don't 115:13 know how Mark did it. You would have to ask him. But I can 115:14 only tell you when I read that, I would think, in a defensive	03_21_18 combo.10

03_21_18 combo-Greer 08-11-14 Booker Depo Designations Final

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140:7 - 140:10	<p>115:15 position, where a competitor is bringing up the subject that</p> <p>115:16 the purpose of the MAUDE database is not to bash the other</p> <p>115:17 filters, which I previously stated, but to illustrate there's</p> <p>115:18 not a perfect filter and there's ongoing reporting database.</p> <p>Greer, Jason 08-11-2014 (00:00:12)</p> <p>140:7 the legs were reformed to help make the device stronger. I</p> <p>140:8 haven't sold one device ever that the company isn't working on</p> <p>140:9 getting improvements to the product based on their failure</p> <p>140:10 rates.</p>	03_21_18 combo.11
145:15 - 145:15	<p>Greer, Jason 08-11-2014 (00:00:02)</p> <p>145:15 Q. Let's mark this as Exhibit No. 7, I believe.</p>	03_21_18 combo.12
146:5 - 147:9	<p>Greer, Jason 08-11-2014 (00:01:26)</p> <p>146:5 Q. Do you agree that this is an e-mail from you dated</p> <p>146:6 March 16, 2006, to Janet Hudnall?</p> <p>146:7 A. Yes.</p> <p>146:8 Q. Okay. See this paragraph here I'm pointing to?</p> <p>146:9 A. (Reviews.) Yeah.</p> <p>146:10 Q. Okay. Can you read that e-mail to the jury, please?</p> <p>146:11 A. Sure. "I was thinking how far we've come in a year</p> <p>146:12 as" --</p> <p>146:13 Q. I'm sorry. Start at the beginning, "By the way."</p> <p>146:14 A. By the way, you know what I was thinking about</p> <p>146:15 today. I was thinking about how far we've come in a year as</p> <p>146:16 far as filter problems. I know we are having a few problems,</p> <p>146:17 but do you freaking remember what it was like a year ago? Do</p> <p>146:18 you remember what it was like two years ago? I don't know if</p> <p>146:19 it can get any worse. You weathered the storm as well as</p> <p>146:20 anyone -- anyone could have. If you do decide to interview</p> <p>146:21 for new positions, you better document what you did because I</p> <p>146:22 don't think there are many better business case studies for a</p> <p>146:23 terrible situation that was held together with scotch tape,</p> <p>146:24 smoke, mirrors, crying, et cetera. You should be pretty proud</p> <p>146:25 of yourself.</p> <p>147:1 Q. In this e-mail you are referring to Bard's filters.</p> <p>147:2 Right?</p> <p>147:3 A. Yeah.</p> <p>147:4 Q. And at that time, it was the Recovery filter that you</p> <p>147:5 were referring to. Correct?</p> <p>147:6 A. Yes.</p> <p>147:7 Q. Okay. And you are stating that in 2004, the</p>	03_21_18 combo.13

03_21_18 combo-Greer 08-11-14 Booker Depo Designations Final

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147:20 - 148:2	<p>147:8 situation was bad; in 2005, it was terrible. Right?</p> <p>147:9 A. That's correct. It was -- it was rough.</p> <p>Greer, Jason 08-11-2014 (00:00:35)</p> <p>147:20 Q. In this e-mail are you stating that</p> <p>147:21 Janet Hudnall held together the Recovery filter situation in</p> <p>147:22 2004 and 2005 with scotch tape, smoke, mirrors, crying,</p> <p>147:23 et cetera?</p> <p>147:24 A. I would say that we all take patient complications</p> <p>147:25 very hard. And then it was an incredibly emotional time where</p> <p>148:1 our customers were emotional. And holding all of that together</p> <p>148:2 was -- was difficult.</p>	03_21_18 combo.14
148:18 - 148:22	<p>Greer, Jason 08-11-2014 (00:00:17)</p> <p>148:18 In this e-mail, are you</p> <p>148:19 stating that -- to Janet Hudnall, that in 2004 and 2005 she</p> <p>148:20 held together a terrible situation regarding the Recovery</p> <p>148:21 filter with scotch tape, smoke, mirrors, crying, et cetera?</p> <p>148:22 A. That's what is written there, yes, sir.</p>	03_21_18 combo.16
170:3 - 170:6	<p>Greer, Jason 08-11-2014 (00:00:09)</p> <p>170:3 Q. Do you have any reason to believe that you would have</p> <p>170:4 ever warned a physician that the Recovery filter had a higher</p> <p>170:5 reported failure rate than other devices?</p> <p>170:6 A. No. I don't think so.</p>	03_21_18 combo.21

PlaintiffsDesignations = 00:02:16

Defense Designations = 00:02:26

Total Time = 00:04:42

EXHIBIT N

Designation Run Report

Ganser 10-11-16 Booker Depo Designations Final 2.1

Ganser, Christopher 10-11-2016

Plaintiffs Designations 00:09:39

Defense Designations 00:00:06

Plaintiffs Counters 00:00:14

Defense Designations 00:06:24

Total Time 00:16:23



3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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6:24 - 7:2	Ganser, Christopher 10-11-2016 (00:00:03) 6:24 Q. State your full name, please, for the 7:1 record. 7:2 A. Christopher David Ganser.	3_21_18 combo Final2_1.1
44:13 - 44:18	Ganser, Christopher 10-11-2016 (00:00:14) 44:13 Q. I keep hearing that one of the benefits 44:14 was -- I mean, these weren't being put in patients for 44:15 the folly of just taking them out, right? That wasn't 44:16 the purpose of putting them in, just to put them in and 44:17 let's see if we can take them out later. I'm not being 44:18 facetious about that.	3_21_18 combo Final2_1.5
44:18 - 44:23	Ganser, Christopher 10-11-2016 (00:00:14) 44:18 That wasn't the purpose for 44:19 these things being implanted, true? 44:20 A. The purpose was, as we have agreed, was 44:21 to, you know, trap clot burden, lyse the clot burden, 44:22 prevent that clot from migrating to the heart. That 44:23 was the purpose of the filter.	3_21_18 combo Final2_1.6
46:1 - 46:5	Ganser, Christopher 10-11-2016 (00:00:11) 46:1 Q. And do you agree that the consequence of 46:2 a product being adulterated is that it may not be 46:3 marketed until and unless it's adulterated quality is 46:4 rectified? 46:5 A. Yes.	3_21_18 combo Final2_1.7
49:6 - 49:8	Ganser, Christopher 10-11-2016 (00:00:03) 49:6 Q. And you agree that the company is 49:7 required to follow this law? 49:8 A. Yes.	3_21_18 combo Final2_1.8
50:11 - 50:24	Ganser, Christopher 10-11-2016 (00:00:40) 50:11 Sir, on the issue of the substantial 50:12 equivalence, do you agree that a manufacturer who 50:13 submits a 510(k) application must assure that any 50:14 device submitted under the 510(k) route be as safe and 50:15 effective as its predicate device and not raise new 50:16 questions about safety or effectiveness? 50:17 A. I believe that's a requirement. 50:18 Q. And that should maintain itself 50:19 throughout the life of the product, right, not just for 50:20 purposes of getting clearance. It should maintain that 50:21 quality throughout the life of the device that got	3_21_18 combo Final2_1.9

3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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50:22 cleared through the 510(k); wouldn't you agree with
50:23 that?

50:24 A. Yes.

51:1 - 51:4

Ganser, Christopher 10-11-2016 (00:00:10)

3_21_18 combo Final2_1.10

51:1 Q. Because to get 510(k) clearances, you

51:2 don't have to do a clinical trial, right?

51:3 A. It depends upon the device and what the

51:4 FDA requirements are.

53:8 - 54:1

Ganser, Christopher 10-11-2016 (00:01:01)

3_21_18 combo Final2_1.12

53:8 Q. And in the instance of the Recovery

53:9 filter, the bench testing was represented to FDA as

53:10 being -- the results being that it was equivalent for

53:11 migration to the Simon Nitinol filter?

53:12 A. Again, without looking at the 510(k), I

53:13 can't say that specifically. I would assume it did.

53:14 Q. I mean, you would have had to, or you

53:15 wouldn't have got 510(k) clearance?

53:16 A. Right.

53:17 Q. But you and I agree that the bench

53:18 testing is not the be all, end all. You've now got to

53:19 see whether or not the bench testing plays itself out

53:20 in the real clinical world once it gets implanted in

53:21 patients, right?

53:22 A. You have to -- you have to monitor the

53:23 product and as part of a postmarketing surveillance

53:24 process and make a determination is the product as good

54:1 as what you tried to determine on the bench.

54:2 - 54:14

Ganser, Christopher 10-11-2016 (00:00:25)

3_21_18 combo Final2_1.13

54:2 Q. And on the bench it seemed that the

54:3 Recovery filter was just as good as the Simon Nitinol

54:4 filter when it came to migration resistance, right?

54:5 A. Again, without having the data in front

54:6 of me to look at, it seems just as good. That's kind

54:7 of a vague term.

54:8 Q. Well, how about substantially

54:9 equivalent?

54:10 A. Substantially equivalent, again, we

54:11 wouldn't have gotten the indication if it wasn't.

54:12 Q. Right, and it didn't raise new issues of

54:13 safety and effectiveness?

3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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54:15 - 54:19	<p>54:14 A. It did not.</p> <p>Ganser, Christopher 10-11-2016 (00:00:17)</p> <p>54:15 Q. But, actually, when the Recovery filter</p> <p>54:16 started being implanted in patients after the 510(k)</p> <p>54:17 clearance, it did start to show new signs of safety and</p> <p>54:18 effectiveness issues that were different than the Simon</p> <p>54:19 Nitinol filter, true?</p>	3_21_18 combo Final2_1.14
54:20 - 54:21	<p>Ganser, Christopher 10-11-2016 (00:00:01)</p> <p>54:20 A. We started receive --</p> <p>54:21 Q. Sir, is that true?</p>	3_21_18 combo Final2_1.15
54:22 - 54:24	<p>Ganser, Christopher 10-11-2016 (00:00:08)</p> <p>54:22 A. We started seeing complaints associated</p> <p>54:23 with Recovery migration that we had not experienced</p> <p>54:24 previously with the Simon Nitinol filter.</p>	3_21_18 combo Final2_1.16
55:1 - 55:10	<p>Ganser, Christopher 10-11-2016 (00:00:26)</p> <p>55:1 Q. So there was evidence early on that</p> <p>55:2 there may have been new questions about safety and the</p> <p>55:3 effectiveness of the Recovery filter when compared to</p> <p>55:4 the Simon Nitinol filter?</p> <p>55:5 A. I don't know if it was compared to the</p> <p>55:6 Simon Nitinol filter. The questions were especially</p> <p>55:7 related to the migrations that we had early on about</p> <p>55:8 what was causing these migrations and what were the</p> <p>55:9 circumstances contributing to the migrations and an</p> <p>55:10 investigation was warranted.</p>	3_21_18 combo Final2_1.17
55:14 - 55:21	<p>Ganser, Christopher 10-11-2016 (00:00:28)</p> <p>55:14 Q. Isn't it true that once the Recovery</p> <p>55:15 filter was cleared in the real clinical world, in</p> <p>55:16 patients in whom these were being implanted, that it</p> <p>55:17 raised new questions about the safety and effectiveness</p> <p>55:18 of the Recovery filter as it compares to the history</p> <p>55:19 that you had with the Simon Nitinol filter; is that</p> <p>55:20 true or false?</p> <p>55:21 A. That's true.</p>	3_21_18 combo Final2_1.18
59:4 - 59:6	<p>Ganser, Christopher 10-11-2016 (00:00:23)</p> <p>59:4 Q. Okay. 517 is a guidance document. Here</p> <p>59:5 you go, take a look. Entitled "Device Labeling</p> <p>59:6 Guidance #G91-one."</p>	3_21_18 combo Final2_1.21 _2_GANSER.1.1
63:3 - 63:14	<p>Ganser, Christopher 10-11-2016 (00:00:34)</p> <p>63:3 Q. For example, a guidance document or even</p>	3_21_18 combo Final2_1.23 _2_GANSER.8.1

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63:4 a federal regulation may not give you the specifics
 63:5 about what you can do to warn, to precaution, to get
 63:6 messages out to doctors and patients about important
 63:7 safety information, but you still are required to
 63:8 follow the best means possible to get that information
 63:9 out?
 63:10 A. It's up to the company to make that
 63:11 determination, what's the best way to communicate any
 63:12 potential hazards and risks associated with hazards of
 63:13 their devises. It's really up to the company to do
 63:14 that.

61:16 - 61:18

Ganser, Christopher 10-11-2016 (00:00:07)

3_21_18 combo Final2_1.22

61:16 Q. And they can actually send out e-mail
 61:17 blasts to doctors, right?

clear

61:18 A. They could.

78:19 - 79:3

Ganser, Christopher 10-11-2016 (00:00:25)

3_21_18 combo Final2_1.35

78:19 Q. But Bard never recommended, as far as
 78:20 you know in the label or anywhere else, that patients
 78:21 ought to be followed periodically to see whether or not
 78:22 the device was staying stable within the cava or
 78:23 whether or not it was actually starting to tilt or
 78:24 perforate or cause -- or move in some way that was
 79:1 putting the patient at increased risk, right?

79:2 A. I believe that information was not in
 79:3 the label.

81:17 - 82:1

Ganser, Christopher 10-11-2016 (00:00:19)

3_21_18 combo Final2_1.36

81:17 I said they also could have put in a
 81:18 patient brochure evidence of a 15-degree tilt or
 81:19 migration of the device downwards or a combination of
 81:20 those two things could be putting the patient at
 81:21 increased risk of perforations, migrations, fracture
 81:22 and bleeding; that could have also been put in a
 81:23 patient brochure?

81:24 A. It could have been put in a patient
 82:1 brochure.

94:21 - 95:9

Ganser, Christopher 10-11-2016 (00:00:45)

3_21_18 combo Final2_1.39

94:21 I want to know whether or not like, for
 94:22 example, if you had a complaint file with all the
 94:23 details in a complaint file about a death, were the
 94:24 details of that shared with the doctors and the

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95:1 community that were putting in these devices or were
95:2 being at least, you know, marketed to put in the
95:3 devices?

95:4 A. Bard would not share the complaint file.

95:5 Q. As a matter of fact, Bard's policy was
95:6 not to share any of its internal trending and reporting
95:7 rates analysis with anyone, true?

95:8 A. That information was kept inside the
95:9 company.

120:5 - 121:3

Ganser, Christopher 10-11-2016 (00:01:26)

3_21_18 combo Final2_1.43

120:5 maybe you can describe,
120:6 how did this work? I mean, were you like the conduit
120:7 or the liaison between the people that were working on
120:8 this at Bard Peripheral Vascular and some of the other
120:9 corporate folks at C.R. Bard? I'm trying to figure --
120:10 can you describe how you fit into this process of
120:11 decision-making and analysis?
120:12 A. Well, again, as the head of quality
120:13 assurance, the division heads of quality assurance such
120:14 as the head of quality of Bard Peripheral Vascular
120:15 division reported to me, we would have reviews, quality
120:16 system reviews, one of which would include complaints
120:17 and adverse events. We'd talk about product
120:18 performance, and if there were certain products that we
120:19 were seeing new or unanticipated trends, especially new
120:20 products or higher risk products, we would have
120:21 discussions about those products and what was being
120:22 done about it and in some cases if the product -- the
120:23 product resulted in significant issues, such as death
120:24 or serious adverse events, there were procedures in
121:1 place from the corporate office that had to be followed
121:2 to conduct investigations and to determine the level of
121:3 remedial action that was required.

121:12 - 122:2

Ganser, Christopher 10-11-2016 (00:00:41)

3_21_18 combo Final2_1.44

121:12 Q. And as the head of regulatory sciences
121:13 during this period of time we've been talking about,
121:14 2003, 2007, 2008, you know, during the time period you
121:15 were there and Bard was selling IVC filters, what kind
121:16 of information were you evaluating to make a decision
121:17 on whether or not you were selling a misbranded or

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	121:18 adulterated product or, frankly, a product that should 121:19 have been recalled? 121:20 A. Whether the product was manufactured in 121:21 accordance with its design specifications. 121:22 Q. Okay. 121:23 A. And whether or not the product was 121:24 performing. 122:1 Q. Performing? 122:2 A. As intended.	
122:4 - 122:11	Ganser, Christopher 10-11-2016 (00:00:28) 122:4 A. And then any risk-benefit issues that 122:5 might arise, was the product creating greater risk over 122:6 the benefits that the product provided, and that would 122:7 be all summarized in an investigation that would be 122:8 sent to a corporate product assessment team, which the 122:9 corporate product assessment team would ultimately 122:10 either concur or not concur with a recommendation from 122:11 the division	3_21_18 combo Final2_1.45
124:2 - 124:10	Ganser, Christopher 10-11-2016 (00:00:23) 124:2 Q. And, certainly, if any of those tests 124:3 would reveal that under reasonably foreseeable uses it 124:4 was not meeting its performance specifications, that 124:5 would be a reason not to continue to sell it, right? 124:6 A. It could be. 124:7 Q. I mean, I think the statute -- I think 124:8 the regulations require you to stop selling it, right? 124:9 A. If it's adulterated, doesn't meet its 124:10 original performance and specifications, yes.	3_21_18 combo Final2_1.46
125:12 - 125:18	Ganser, Christopher 10-11-2016 (00:00:15) 125:12 Q. Well, let me ask you, what do you do 125:13 under those circumstances when you find out it did not 125:14 meet its performance specifications? 125:15 A. We try to look at the test data, we try 125:16 to ask ourselves what variables are influencing that 125:17 test. We try to compare that test for what we know in 125:18 the field.	3_21_18 combo Final2_1.128
272:14 - 272:15	Ganser, Christopher 10-11-2016 (00:00:17) 272:14 Q. Exhibit 530. Exhibit 530 is an 272:15 August 25 e-mail.	
273:19 - 273:19	Ganser, Christopher 10-11-2016 (00:00:00)	3_21_18 combo Final2_1.124

3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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273:21 - 273:22	273:19 Do you see where I am? Ganser, Christopher 10-11-2016 (00:00:03) 273:21 THE WITNESS: I do. And, again, this is 273:22 the first time I've seen this.	3_21_18 combo Final2_1.125
291:14 - 292:3	Ganser, Christopher 10-11-2016 (00:00:50) 291:14 Q. Okay. 533. I only have one copy of 291:15 that one, I'm sorry. 291:16 This is an HHE, February 15, 2006. 291:17 Have you seen this before? 291:18 A. I would have. 291:19 Q. And this is a -- I think we talked about 291:20 this earlier. This is in February of 2006. This is 291:21 about six months after the G2 was cleared by FDA? 291:22 A. It was. 291:23 Q. This deals with G2 inferior vena cava 291:24 migrations? 292:1 A. Migrations, both cephaladic and caudal. 292:2 I believe this was written as part of investigation 292:3 related to caudal migrations.	3_21_18 combo Final2_1.131
294:4 - 294:9	Ganser, Christopher 10-11-2016 (00:00:18) 294:4 Q. And, again, is this information that you 294:5 advised doctors or patients that the G2 within six 294:6 months of it being released on the market, cleared to 294:7 premarketing, was experiencing undesirable risks of 294:8 caudal migration? 294:9 A. No.	3_21_18 combo Final2_1.132
298:3 - 298:4	Ganser, Christopher 10-11-2016 (00:00:06) 298:3 MR. LOPEZ: One final document, at least 298:4 at this time. Exhibit 534.	3_21_18 combo Final2_1.135 ...36, GANSER.1
299:1 - 299:6	Ganser, Christopher 10-11-2016 (00:00:17) 299:1 Q. Okay. Well, I mean, you knew that after 299:2 that -- at least that HHE that I just showed you, that 299:3 like the Recovery filter, that the company was in the 299:4 process of looking at the design of the G2 to determine 299:5 how it could be redesigned? 299:6 A. Yes.	3_21_18 combo Final2_1.136 clear
301:1 - 301:3	Ganser, Christopher 10-11-2016 (00:00:13) 301:1 Q. And it knew that it had an undesirable 301:2 risk profile based on its own R002 that Dr. -- from 301:3 Dr. Ciavarella's February 2006 HHE?	3_21_18 combo Final2_1.137

3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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301:5 - 301:13	Ganser, Christopher 10-11-2016 (00:00:22) 301:5 BY MR. LOPEZ: 301:6 Q. Undesirable? 301:7 A. It was rated undesirable per the 301:8 remedial action plan process. 301:9 Q. Yeah, and it was obviously rated as 301:10 something that needed to be redesigned to deal with 301:11 that -- those undesirable complications, true? 301:12 A. It needed to be addressed. 301:13 Q. Well, it needed to be redesigned, right?	3_21_18 combo Final2_1,138
301:15 - 301:21	Ganser, Christopher 10-11-2016 (00:00:14) 301:15 BY MR. LOPEZ: 301:16 Q. There were some defects in the design of 301:17 the G2 that was leading to the problems described in 301:18 Dr. Civarella's February 2006 HHE; don't you agree, 301:19 sir? 301:20 A. There were issues with the design that 301:21 needed to be addressed.	3_21_18 combo Final2_1,139
302:14 - 302:21	Ganser, Christopher 10-11-2016 (00:00:26) 302:14 Q. All right. So did you, as the vice 302:15 president of regulatory sciences after learning all you 302:16 learned about the complications associated with the G2 302:17 filter shortly after it was launched and cleared take 302:18 any steps to put a product quality hold on it or to 302:19 recall it or to stop selling it so that you could fix 302:20 those problems? 302:21 A. No.	3_21_18 combo Final2_1,140
307:8 - 307:9	Ganser, Christopher 10-11-2016 (00:00:06) 307:8 What information does Bard have about 307:9 the effectiveness or the benefits of its IVC filters?	3_21_18 combo Final2_1,173
307:11 - 307:21	Ganser, Christopher 10-11-2016 (00:00:39) 307:11 THE WITNESS: What Bard has is -- and 307:12 what Bard uses, whether it be our medical 307:13 director, our R&D people, or even our quality 307:14 people, regulatory people is information 307:15 generated from the field, information generated 307:16 from clinical literature that talks about 307:17 complications and solutions to certain patients 307:18 that have deep vein thrombus and who have no 307:19 other treatment options and whether or not	3_21_18 combo Final2_1,149

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322:11 - 323:17

307:20 those products are performing appropriately in
307:21 the absence of complaint information.

Ganser, Christopher 10-11-2016 (00:01:38)

3_21_18 combo Final2_1,167

322:11 Q. Now, in the course of your
322:12 investigations with the team on the Recovery filter
322:13 that you've talked about a lot today, did you meet with
322:14 people who represented all departments of Bard with
322:15 respect to the Recovery filter?

322:16 A. All the relevant departments which
322:17 typically would have included R&D, regulatory affairs,
322:18 quality engineering, marketing, medical, clinical.

322:19 Q. And did you believe that you had the
322:20 best talent together for that investigation of Recovery
322:21 that Bard had to offer?

322:22 A. We put the best talent available to
322:23 conduct this investigation.

322:24 Q. And then did you do any work seeking
323:1 information from outside Bard relative to Recovery?

323:2 A. We did. We had medical consultants, I
323:3 believe one was Dr. John Kaufman, another was Dr. Tony
323:4 Venbrux. We also convened clinical panels one time in
323:5 Chicago. We also convened a panel of bariatric
323:6 surgeons to get their input about the product and
323:7 issues related to the product.

323:8 Q. And with respect to the representatives
323:9 from departments within Bard who were a part of the
323:10 investigation process, did you feel that those
323:11 individuals had sufficient input to the process?

323:12 A. They did.

323:13 Q. And did you feel that all of those
323:14 departments were genuinely bringing the best
323:15 information and best recommendations they had about the
323:16 filter to those meetings and investigations?

323:17 A. I do, I do.

324:2 - 324:9

Ganser, Christopher 10-11-2016 (00:00:28)

3_21_18 combo Final2_1,168

324:2 Q. And why not?

324:3 A. Because I firmly believe, as did many of
324:4 the people that were working on this investigation or
324:5 involved with Recovery filter, the product still
324:6 provided a great benefit to patients who had no

3_21_18 combo Final2_1-Ganser 10-11-16 Booker Depo Designations Final 2.1

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324:7 alternative therapies, and the benefits clearly
324:8 outweighed the risks that were being reported in the
324:9 adverse events reporting database.

Plaintiffs Designations = 00:09:39

Defense Designations = 00:00:06

Plaintiffs Counters = 00:00:14

Defense Designations = 00:06:24

Total Time = 00:16:23

Documents Shown

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EXHIBIT O

Designation Run Report

Rogers 03_21_18 Booker Depo Trial Run Final2

Rogers, Frederick 07-18-2017

Our Designations 00:08:08

Their Designations 00:02:41

Total Time 00:10:49



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46:6 - 46:9	Rogers, Frederick 07-18-2017 (00:00:13) 46:6 Q. Now, do you understand that this 46:7 deposition that you're giving today is to discuss 46:8 Bard and its IVC filters? 46:9 A. Yes.	03_22_18 Final.1
60:22 - 60:25	Rogers, Frederick 07-18-2017 (00:00:12) 60:22 Q. Did Bard ever come to you and request 60:23 that you conduct a clinical trial or perform a trial 60:24 study of any of its filters? 60:25 A. Not that I recall.	03_22_18 Final.2
61:8 - 61:25	Rogers, Frederick 07-18-2017 (00:01:02) 61:8 Q. When you met with the panel at the 61:9 Bard summit we discussed a while ago, do you recall 61:10 any discussions about Bard performing a clinical 61:11 trial or undertaking a trial study of any of its 61:12 filters? 61:13 A. I don't recall specifically any 61:14 discussions to that extent. But I will say that 61:15 I've had a longstanding interest in doing a study on 61:16 the effectiveness of filters and, specifically, in 61:17 trauma patients. I may have talked to Bard about 61:18 that. I don't recall. 61:19 Q. You may have spoken to Bard about 61:20 that? 61:21 A. Yes, sir. 61:22 Q. But they have never, in turn, 61:23 requested that you conduct such a study of its 61:24 filters, for example, correct? 61:25 A. Not that I recall.	03_22_18 Final.3
67:25 - 68:3	Rogers, Frederick 07-18-2017 (00:00:14) 67:25 Q. And if the filter did not stay in 68:1 place and migrated up to the heart, what safety risk 68:2 would be associated with a Bard filter under those 68:3 circumstances?	03_22_18 Final.4
68:5 - 68:8	Rogers, Frederick 07-18-2017 (00:00:18) 68:5 THE WITNESS: If it migrated to the 68:6 heart, it could -- it could cause an arrhythmia, it 68:7 could cause tamponade. Those would be the two big 68:8 concerns with a filter that moved to the heart.	03_22_18 Final.5
106:10 - 106:14	Rogers, Frederick 07-18-2017 (00:00:20)	03_22_18 Final.6

03_22_18 Final-Rogers 03_21_18 Booker Depo Trial Run Final2

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106:10 - 106:19	<p>106:10 Q. Doctor, it's my understanding that</p> <p>106:11 you are an author on an article titled, Vena Cava</p> <p>106:12 Filter Use in Trauma and Rates of Pulmonary</p> <p>106:13 Embolism, 2003 to 2015?</p> <p>106:14 A. Yes, sir.</p> <p>Rogers, Frederick 07-18-2017 (00:00:05)</p>	03_22_18 Final.7
107:1 - 107:13	<p>106:18 MR. JOHNSON: And, Amanda, we would</p> <p>106:19 like to mark that as Exhibit-4053, please.</p> <p>Rogers, Frederick 07-18-2017 (00:00:39)</p> <p>107:1 Q. Doctor, take a minute and just</p> <p>107:2 confirm that that is the article you are an author</p> <p>107:3 on.</p> <p>107:4 A. Yes, I recognize the article.</p> <p>107:5 Q. It was published in May -- I'm sorry,</p> <p>107:6 on May 17th, 2017, in JAMA?</p> <p>107:7 A. JAMA Surgery.</p> <p>107:8 Q. JAMA Surgery. And JAMA stands for</p> <p>107:9 the Journal of the American Medical Association?</p> <p>107:10 A. Correct.</p> <p>107:11 Q. And the article spans 12 years and</p> <p>107:12 involved many patients; is that correct?</p> <p>107:13 A. Yes.</p>	03_22_18 Final.8
108:23 - 108:25	<p>Rogers, Frederick 07-18-2017 (00:00:08)</p> <p>108:23 Q. I'd like to have at least an estimate</p> <p>108:24 as to how many trauma patients were analyzed with</p> <p>108:25 respect to this article.</p>	03_22_18 Final.9
109:5 - 109:6	<p>Rogers, Frederick 07-18-2017 (00:00:03)</p> <p>109:5 THE WITNESS: Probably close to 30</p> <p>109:6 million.</p>	03_22_18 Final.10
110:14 - 110:15	<p>Rogers, Frederick 07-18-2017 (00:00:06)</p> <p>110:14 Q. This article was designed to study</p> <p>110:15 the effectiveness of IVC filters, correct?</p>	03_22_18 Final.24
110:17 - 110:19	<p>Rogers, Frederick 07-18-2017 (00:00:07)</p> <p>110:17 THE WITNESS: No, I disagree with</p> <p>110:18 that characterization. We were just noting temporal</p> <p>110:19 trends in filter use during that time period.</p>	03_22_18 Final.25
114:21 - 114:23	<p>Rogers, Frederick 07-18-2017 (00:00:11)</p> <p>114:21 Q. And do you consider trauma patients</p> <p>114:22 as a whole to be at highest risk for PE compared to</p> <p>114:23 other patient populations?</p>	03_22_18 Final.11

03_22_18 Final-Rogers 03_21_18 Booker Depo Trial Run Final2

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114:25 - 115:1	Rogers, Frederick 07-18-2017 (00:00:04) 114:25 THE WITNESS: I would say one of the 115:1 highest risk groups of patients, yes.	03_22_18 Final.12
116:7 - 116:11	Rogers, Frederick 07-18-2017 (00:00:14) 116:7 Q. All right. And does that data 116:8 identify the type of filter involved in the patients 116:9 that were assessed for purposes of writing this 116:10 article? 116:11 A. No.	03_22_18 Final.26
117:4 - 118:5	Rogers, Frederick 07-18-2017 (00:01:24) 117:4 Q. And at the time you and your 117:5 colleagues began the study, there had been a 117:6 precipitous drop in the use of IVC filters in trauma 117:7 patients, correct? 117:8 A. Well, that's what the purpose of the 117:9 study was, was to look at the temporal trends in 117:10 vena cava filter use. 117:11 We had a perception that there may be 117:12 less filters being put in. But until we, you know, 117:13 actually did the study and analyzed the data did we 117:14 know for sure. 117:15 Q. And you, in fact, found that there 117:16 had been a significant decline or drop in the use of 117:17 IVC filters in trauma patients, correct? 117:18 A. Yes, correct. 117:19 Q. All right. And when you and your 117:20 colleagues embarked on this article, you were 117:21 expecting to see a rise or an increase in the rate 117:22 of pulmonary embolism because of this significant 117:23 drop in the use of IVC filters, correct? 117:24 A. Correct. 117:25 Q. That was your prediction, if you 118:1 will, or your hypothesis at the start of this? 118:2 A. Yes, sir. 118:3 Q. And while it might have been a guess, 118:4 it was felt to be an educated guess, that is, your 118:5 hypothesis? 118:7 - 118:12 Rogers, Frederick 07-18-2017 (00:00:14) 118:7 THE WITNESS: Yes. 118:8 BY MR. JOHNSON:	03_22_18 Final.13
118:7 - 118:12	Rogers, Frederick 07-18-2017 (00:00:14) 118:7 THE WITNESS: Yes. 118:8 BY MR. JOHNSON:	03_22_18 Final.14

03_22_18 Final-Rogers 03_21_18 Booker Depo Trial Run Final2

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118:9 - 118:12	Q. And that's why you do the study, because unless you do the study predicting an outcome, there's nothing more than speculation and conjecture, correct?	
118:14 - 118:23	Rogers, Frederick 07-18-2017 (00:00:35) THE WITNESS: I think that's fair, yes. BY MR. JOHNSON: Q. And that hypothesis was proven to be not true, correct? A. Correct. Q. That is, what you and your colleagues found was that, despite the significant decline in the use of IVC filters in trauma patients, there was no change in the rate of PE, correct?	03_22_18 Final.15
118:25 - 118:25	Rogers, Frederick 07-18-2017 (00:00:01) THE WITNESS: Correct.	03_22_18 Final.16
119:2 - 119:5	Rogers, Frederick 07-18-2017 (00:00:14) Q. So you and your colleagues determined that because of these findings, IVC filters may have limited utility in influencing the rates of pulmonary embolism, correct?	03_22_18 Final.27
119:7 - 119:11	Rogers, Frederick 07-18-2017 (00:00:14) THE WITNESS: Yes. I think the operative word here is "may." Because we just don't know, in a large patient population like this, any individual patient who may or may not benefit from a filter.	03_22_18 Final.28
119:17 - 119:24	Rogers, Frederick 07-18-2017 (00:00:25) Q. That's a pretty large patient population, isn't it? A. It certainly is, yes. Q. And what you folks -- and I'm referring to you and your colleagues -- found was that despite the significant decline in IVC filter use in trauma patients, there was no change in the rate of pulmonary embolism, correct?	03_22_18 Final.17
120:1 - 120:1	Rogers, Frederick 07-18-2017 (00:00:02) THE WITNESS: Correct.	03_22_18 Final.18
120:3 - 120:7	Rogers, Frederick 07-18-2017 (00:00:18)	03_22_18 Final.29

Page/Line	Source	ID
120:3 - 120:21	<p>120:3 Q. And when you and your colleagues 120:4 determined that filters may have limited utility, 120:5 what you're referring to is they may not be 120:6 effective in influencing the rates of pulmonary 120:7 embolism in trauma patients?</p> <p>Rogers, Frederick 07-18-2017 (00:00:48)</p> <p>120:9 THE WITNESS: What we concluded, 120:10 based on this study, was that as it currently 120:11 stands, we are not doing a very good job in 120:12 identifying which patients would benefit from a vena 120:13 cava filter. I think we need to -- I think this 120:14 study generates more questions about what -- who is 120:15 best served by having a prophylactic vena cava 120:16 filter placed. 120:17 BY MR. JOHNSON: 120:18 Q. And that's because in your article, 120:19 based on your study of all of these trauma patients, 120:20 the placement of IVC filters did not improve the 120:21 rates of pulmonary embolism, correct?</p>	03_22_18 Final.30
120:23 - 121:5	<p>Rogers, Frederick 07-18-2017 (00:00:25)</p> <p>120:23 THE WITNESS: Overall -- the overall 120:24 rate. But, again, as was noted in the study, the 120:25 real purpose of vena cava filters is to prevent 121:1 fatal PEs. We do not know, based on this study, 121:2 whether or not vena cava filters were effective in 121:3 decreasing the rate of fatal PE, which is an 121:4 important -- you know, an important limitation of 121:5 this study.</p>	03_22_18 Final.31
125:3 - 125:6	<p>Rogers, Frederick 07-18-2017 (00:00:21)</p> <p>125:3 Q. And what have you done to 125:4 better define or to optimize patient selection to 125:5 determine whether that patient is a candidate for 125:6 IVC filter implantation?</p>	03_22_18 Final.19
125:8 - 125:18	<p>Rogers, Frederick 07-18-2017 (00:00:48)</p> <p>125:8 THE WITNESS: Well, since this 125:9 article was published, I've, you know -- I've made 125:10 it my life's work to try to identify who best would 125:11 be served by a vena cava filter. 125:12 Have I done it perfectly? Obviously 125:13 not, because there still are patients who get PEs</p>	03_22_18 Final.20

03_22_18 Final-Rogers 03_21_18 Booker Depo Trial Run Final2

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125:14 - 125:22	<p>125:14 despite the fact that, you know, we characterize 125:15 them as intermediate risk. And, you know, I think 125:16 this study was a bit of an eye-opener for me because 125:17 I really did expect that filters would impact the 125:18 rate of PE.</p> <p>Rogers, Frederick 07-18-2017 (00:00:07)</p> <p>125:19 So we have to go back to the drawing 125:20 board and re-look at that. That's how -- 125:21 Q. And -- 125:22 A. That's how medicine advances.</p>	03_22_18 Final.32
126:6 - 126:10	<p>Rogers, Frederick 07-18-2017 (00:00:20)</p> <p>126:6 Q. And, Doctor, it was an eye-opener for 126:7 you because you were expecting this study to 126:8 establish that the use of filters in trauma patients 126:9 would, in fact, improve the rates of pulmonary 126:10 embolism, correct?</p>	03_22_18 Final.21
126:12 - 126:16	<p>Rogers, Frederick 07-18-2017 (00:00:18)</p> <p>126:12 THE WITNESS: Yes. 126:13 BY MR. JOHNSON: 126:14 Q. And this study that you were part of 126:15 demonstrated that the use of IVC filters did not 126:16 improve the rates of pulmonary embolism, correct?</p>	03_22_18 Final.22
126:19 - 126:19	<p>Rogers, Frederick 07-18-2017 (00:00:01)</p> <p>126:19 Yes.</p>	03_22_18 Final.23
126:19 - 126:20	<p>Rogers, Frederick 07-18-2017 (00:00:04)</p> <p>126:19 THE WITNESS: Yes. As they -- as 126:20 they were identified in these databases.</p>	03_22_18 Final.33

Our Designations = 00:08:08

Their Designations = 00:02:41

Total Time = 00:10:49

EXHIBIT P

Designation Run Report

DeFord_COMBO_R02

DEFORD, John 06-02-2016

PL Affirmatives 00:01:22

DEF Affirmatives 00:11:29

Total Time 00:12:51



DeFord_COMBO_R02-DeFord_COMBO_R02

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10:4 - 10:5	DEFORD, John 06-02-2016 (00:00:02) 10:4 Q. Good morning, Dr. DeFord. 10:5 A. Good morning.	DeFord_COMBO_R02.1
13:6 - 13:15	DEFORD, John 06-02-2016 (00:00:23) 13:6 Q. Why don't you 13:7 explain then what your current position 13:8 is with the company? 13:9 A. Certainly. My -- I believe 13:10 this is probably prior to 2007, because 13:11 my title now is senior vice president for 13:12 science, technology, and clinical 13:13 affairs; and in 2007, the clinical 13:14 affairs piece was added to my 13:15 responsibilities.	DeFord_COMBO_R02.2
20:22 - 21:5	DEFORD, John 06-02-2016 (00:00:14) 20:22 Q. Have you not yourself 20:23 conducted clinical research in 2000-2001 20:24 regarding the use of removable vena cava 21:1 filter for the prevention of pulmonary 21:2 embolus? 21:3 A. There was -- again, it was 21:4 research that was being conducted, yes, 21:5 and I was involved.	DeFord_COMBO_R02.3
103:17 - 103:20	DEFORD, John 06-02-2016 (00:00:07) 103:17 So were you at this point 103:18 still part of the decision making about 103:19 whether or not the product would be 103:20 placed on hold or not?	DeFord_COMBO_R02.7
105:15 - 106:7	DEFORD, John 06-02-2016 (00:00:38) 105:15 Q. And who ultimately made that 105:16 decision? 105:17 A. Well, it's a group decision, 105:18 if you will. The process, though, is one 105:19 where the division assessment team and 105:20 this group would have met and reviewed 105:21 all of the available information. 105:22 My recollection is, we also 105:23 brought in outside clinicians and 105:24 experts, had an expert panel to discuss 106:1 things that we were, again -- didn't	DeFord_COMBO_R02.10

DeFord_COMBO_R02-DeFord_COMBO_R02

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106:2 anticipate with the use of the device;
 106:3 and through all of those discussions, the
 106:4 clinicians strongly recommended and asked
 106:5 us to keep the product available because
 106:6 of the benefits that it brought to
 106:7 patients.

117:6 - 117:11 **DEFORD, John 06-02-2016 (00:00:13)**

DeFord_COMBO_R02 15

117:6 So that's the sixth death
 117:7 and the product is still out in the
 117:8 market, being sold, with no restrictions
 117:9 other than whatever a doctor needs to
 117:10 have to get one in his hands; is that
 117:11 right?

117:7 - 117:11 **DEFORD, John 06-02-2016 (00:00:12)**

DeFord_COMBO_R02 16

117:7 and the product is still out in the
 117:8 market, being sold, with no restrictions
 117:9 other than whatever a doctor needs to
 117:10 have to get one in his hands; is that
 117:11 right?

117:14 - 120:13 **DEFORD, John 06-02-2016 (00:02:18)**

DeFord_COMBO_R02 17

117:14 THE WITNESS: My
 117:15 recollection is, yes; and
 117:16 although, you know, we talked
 117:17 about that first document with the
 117:18 hold, I know there was a lot of
 117:19 discussion and I recall a lot of
 117:20 discussion around each one of
 117:21 these situations and understanding
 117:22 whether it was appropriate to put
 117:23 the product on hold or not.

117:24 So although that first
 118:1 document had that time period and
 118:2 had that stated there, my
 118:3 recollection is that that decision
 118:4 was changed.

118:5 BY MS. BOSSIER:

118:6 Q. Okay. Well, when did that
 118:7 decision change?

118:8 A. I don't recall.

118:9 Q. Who —

DeFord_COMBO_R02-DeFord_COMBO_R02

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118:10 A. I mean --

118:11 Q. -- who changed it and why?

118:12 A. Well, there were a lot of --

118:13 again, a lot of activity and a lot of

118:14 discussion ongoing with the use of the

118:15 device, discussions with clinicians,

118:16 discussions with the FDA, internal

118:17 investigations, health hazard evaluation,

118:18 testing, all of those activities were

118:19 ongoing.

118:20 And my recollection is that

118:21 the company continued to believe that

118:22 even in the face of these events, the

118:23 benefits outweighed the risks of having

118:24 the product.

119:1 And I recall -- I don't

119:2 remember the exact date, but I recall

119:3 having a discussion with a clinician and

119:4 his name was Gary Ansel, he's a

119:5 cardiologist, specifically talking about

119:6 this situation.

119:7 And, again, I don't remember

119:8 the dates, but the -- but the discussion

119:9 was whether the product should come off

119:10 the market or not; and he and other

119:11 physicians, as I recall, said to me

119:12 directly -- and although I wasn't the key

119:13 decision-maker, I was involved -- saying

119:14 this brings value to patients.

119:15 Q. Was that doctor informed

119:16 that there was approximately one death

119:17 per month following the migration

119:18 incident of February 2004 --

119:19 A. I --

119:20 Q. When he made those

119:21 statements?

119:22 A. -- I don't recall the exact

119:23 details, but I'm confident that he had

119:24 knowledge of any complications, which,

120:1 you know, we're talking about here -- and

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120:2 each one of these are tragic events that
 120:3 are happening in a sick patient
 120:4 population in very small numbers,
 120:5 although, as I said, every one of these
 120:6 is a significant event.
 120:7 That, as you can see by
 120:8 these documents, Bard took a lot of time
 120:9 and care trying to analyze each one of
 120:10 these and understand the situations
 120:11 behind them to see if there were specific
 120:12 issues with the product or ways to
 120:13 improve the product.

121:1 - 121:3

DEFORD, John 06-02-2016 (00:00:11)

DeFord_COMBO_R02.10

121:1 At what point did Bard think
 121:2 it was appropriate to take the device off
 121:3 the market and save lives?

121:6 - 122:6

DEFORD, John 06-02-2016 (00:00:46)

DeFord_COMBO_R02.17

121:6 THE WITNESS: Well, first
 121:7 off, I disagree with your comment
 121:8 that the device is killing people.
 121:9 The disease is killing people.
 121:10 The device failed to prevent it.
 121:11 That's a very different thing.
 121:12 The device is still adding
 121:13 value. It couldn't stop a massive
 121:14 thrombus, just like your seatbelt
 121:15 can't stop a train from hitting
 121:16 you and destroying your car. This
 121:17 thing was -- these kind of events
 121:18 were beyond anything that Bard or
 121:19 anyone in the industry to my
 121:20 knowledge knew about.
 121:21 And -- and so it was being
 121:22 evaluated very vigorously. As you
 121:23 can see by this documentation, we
 121:24 were looking at it very closely,
 122:1 very carefully, and trying to
 122:2 understand every single event to
 122:3 put the very best products on the
 122:4 market and keep them as safe as

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122:5 they possibly could be and keep
122:6 patients safe.

129:3 - 129:16

DEFORD, John 06-02-2016 (00:00:32)

DeFord_COMBO_R02 18

129:3 Q. So there were any
129:4 number of migrations -- and we could
129:5 count them all -- even those not
129:6 resulting in death, that occurred after
129:7 the original decision that if one more
129:8 happened, you all would -- Bard would put
129:9 it on hold and that didn't happen.
129:10 A. That's right. The original
129:11 decision was, if we had another one of
129:12 these incidents during the investigation,
129:13 the product would be put on hold; but as
129:14 more information came in and the
129:15 investigation continued, that decision
129:16 was changed.

129:17 - 129:19

DEFORD, John 06-02-2016 (00:00:05)

DeFord_COMBO_R02 19

129:17 Q. And the risk to the patients
129:18 was really not part of that
129:19 consideration, was it?

129:23 - 130:19

DEFORD, John 06-02-2016 (00:00:40)

DeFord_COMBO_R02 20

129:23 I think the risk to
129:24 patients was absolutely evaluated,
130:1 but the decision was made that the
130:2 product continued to add value and
130:3 shouldn't be placed on hold.

130:4 BY MS. BOSSIER:

130:5 Q. Well, if the product had
130:6 been placed on hold, then you would not
130:7 have had a retrievable filter on the
130:8 market. Right?

130:9 A. Well, that's -- that's

130:10 correct, but that -- that wasn't part of
130:11 the analysis, except that clinicians
130:12 wanted a device they could retrieve. It
130:13 wasn't a company decision, well, we're
130:14 not going to put it on hold because we're
130:15 selling a retrievable product.
130:16 It was the belief and our

DeFord_COMBO_R02-DeFord_COMBO_R02

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130:17 continued belief that this product added
130:18 unique, special value and patients' lives
130:19 were being saved.

133:1 - 133:17 **DEFORD, John 06-02-2016 (00:00:37)**

DeFord_COMBO_R02 37

133:1 you said the decision by
133:2 the investigational team to keep the
133:3 product on the market was due to
133:4 physicians wanting to use this device; is
133:5 that right?

133:6 A. That was in part, yes.

133:7 Q. And part of their -- part of
133:8 a physician's decision to want to use a
133:9 device is to know what the risk and
133:10 benefits are. Right?

133:11 A. Sure.

133:12 Q. So the physicians are, in
133:13 your words, asking Bard to keep this
133:14 product on the market so they can keep
133:15 it, but Bard's not telling them for
133:16 almost a year that this device is killing
133:17 apparently one person a month.

133:20 - 135:11 **DEFORD, John 06-02-2016 (00:01:15)**

DeFord_COMBO_R02 38

133:20 THE WITNESS: Well, I

133:21 First, there

133:22 was a tremendous amount of
133:23 discussion with clinicians
133:24 ongoing.

134:1 Did Bard put out a press

134:2 release or a dear doctor letter, I

134:3 believe you and the timing. This

134:4 wasn't happening in a vacuum.

134:5 There was a tremendous amount of

134:6 discussion in the medical

134:7 community about the technology,

134:8 about the use, and about these

134:9 cases, and about these situations.

134:10 So Bard wasn't withholding

134:11 this information. Although Bard

134:12 didn't in a broad way, you know,

134:13 send something out, Bard was

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134:14 actively engaged with the FDA
 134:15 discussing these situations, too,
 134:16 and as you can see in all of this
 134:17 documentation that we have, there
 134:18 was a tremendous amount of
 134:19 activity ongoing that involved
 134:20 clinicians to evaluate the
 134:21 technology, understand the
 134:22 situations, and see what could be
 134:23 done about it.

134:24 BY MS. BOSSIER:

135:1 Q. Well, let's talk about what
 135:2 could be done about it. There's any
 135:3 number of things that could be done about
 135:4 it. I mean, after -- after your initial
 135:5 investigative meeting, the first thing
 135:6 that was decided was, if migration
 135:7 happens one more time and results -- and
 135:8 requires surgical intervention, we're
 135:9 going to put a hold on this product.
 135:10 So that's something Bard
 135:11 could have done. Right?

135:14 - 136:20

DEFORD, John 06-02-2016 (00:00:59)

DeFord_COMBO_R02 26

135:14 THE WITNESS: That was the
 135:15 discussion ongoing, but again
 135:16 let's put this in perspective and
 135:17 try to understand some of the
 135:18 discussion that we were having at
 135:19 that time.

135:20 I understand that roughly
 135:21 200,000 people a year in the U.S.
 135:22 die from a pulmonary embolism and
 135:23 there were deaths associated with
 135:24 the vena cava filter, although,
 136:1 again, I don't think the filter
 136:2 was causing the deaths. The
 136:3 filter was not able to prevent the
 136:4 deaths. But the deaths associated
 136:5 with Bard filters are very, very,
 136:6 very low in the comparison.

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136:7 So, again, from the medical
 136:8 literature, up to 30 percent of
 136:9 patients with recurrent PE, or
 136:10 pulmonary embolism, die. Much
 136:11 less than 1 percent of patients
 136:12 that get a Bard filter have
 136:13 experienced death from a pulmonary
 136:14 embolism.
 136:15 So, again, part of the
 136:16 analysis was that this technology
 136:17 was saving lives and -- and I
 136:18 think your supposition that it's
 136:19 killing patients is certainly not
 136:20 the conclusion we drew.

138:13 - 139:6

DEFORD, John 06-02-2016 (00:00:39)

DeFord_COMBO_R02.01

138:13 Q. You had another product on
 138:14 the market that was just as equally
 138:15 capable, if not better, shown to be
 138:16 better and more capable, of helping
 138:17 patients than the Recovery filter;
 138:18 correct?
 138:19 A. I'm not -- we certainly had
 138:20 another vena cava filter on the market,
 138:21 the Simon Nitinol filter, very different
 138:22 technology, certainly known to prevent
 138:23 pulmonary embolism death, but didn't have
 138:24 all of the features and benefits of
 139:1 Recovery.
 139:2 Q. Okay. I understand it
 139:3 didn't have the bells and whistles of the
 139:4 Recovery, but you are aware that it was a
 139:5 much safer device than the Recovery
 139:6 filter ended up being; correct?

139:21 - 141:5

DEFORD, John 06-02-2016 (00:01:02)

DeFord_COMBO_R02.02

139:21 The Simon Nitinol filter was
 139:22 used in a very different class of
 139:23 patients, as we came to learn,
 139:24 from the Recovery filter. Simon
 140:1 Nitinol primarily used in patients
 140:2 that were -- where retrievability

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140:3 wasn't a concern.
 140:4 And so these were patients
 140:5 that were -- terminal cancer
 140:6 patients, for example, brain
 140:7 cancer, has a high incidence of
 140:8 thrombosis associated with it and
 140:9 so trying to give patients quality
 140:10 of life, other cancers, other
 140:11 neoplasms.
 140:12 And so that technology,
 140:13 although deaths weren't reported,
 140:14 it doesn't -- we didn't believe
 140:15 and still don't believe that it
 140:16 wasn't because deaths didn't
 140:17 occur. It was just these patients
 140:18 were in a terminal state most of
 140:19 the time when they received a
 140:20 Simon Nitinol filter, and so it
 140:21 was a very different class of
 140:22 patients.
 140:23 And so it's kind of trying
 140:24 to compare the technologies that
 141:1 were really designed for different
 141:2 kind of application. Same goal of
 141:3 preventing fatal pulmonary
 141:4 embolism, but used in a different
 141:5 type of situation.

226:14 - 227:10 **DEFORD, John 06-02-2016 (00:00:34)**

226:14 Q. Well, in September of 2015,
 226:15 on the video we just listened to, you
 226:16 stated: They, being the IVC filters, are
 226:17 implanted by physicians only after a
 226:18 careful assessment of the risk and
 226:19 benefits for the individual patient and
 226:20 they should be removed after protection
 226:21 from pulmonary embolism is no longer
 226:22 needed.
 226:23 Correct?
 226:24 A. Correct.
 227:1 Q. And that's what you said in

DeFord_COMBO_R02-DeFord_COMBO_R02

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	227:2 that video; correct?	
	227:3 A. Yes.	
	227:4 Q. Now, that is not something	
	227:5 that you told the doctors in -- in	
	227:6 December of 2004; is that correct?	
	227:7 A. Not in the dear doctor	
	227:8 letter, no.	
	227:9 Q. Or in the IFU.	
	227:10 A. No.	
237:5 - 237:22	DEFORD, John 06-02-2016 (00:00:44)	DeFord_COMBO_R02.07
	237:5 Q. The issue of advising	
	237:6 physicians to monitor patients who have	
	237:7 been implanted with the IVC filter, that	
	237:8 is not a new notion to Bard, is it?	
	237:9 A. I mean, it's not an	
	237:10 immediate notion. I mean, I think any	
	237:11 time a device is used, there should be	
	237:12 monitoring of that technology regardless	
	237:13 of where it's used, and so that's	
	237:14 independent of vena cava filter.	
	237:15 And, again, I would view	
	237:16 that as sort of common knowledge that	
	237:17 you'd want to watch these devices, you	
	237:18 know, whether it's a knee implant, a hip	
	237:19 implant, a stent placed anywhere in the	
	237:20 body, or a vena cava filter.	
	237:21 So the -- certainly the idea	
	237:22 of monitoring is not new.	
237:23 - 238:4	DEFORD, John 06-02-2016 (00:00:15)	DeFord_COMBO_R02.08
	237:23 Q. And it is certainly	
	237:24 something that Bard could have warned	
	238:1 physicians about in 2004; correct?	
	238:2 A. We could have, that's right.	
	238:3 There's a lot of things that we could	
	238:4 have done that we didn't -	
238:5 - 238:12	DEFORD, John 06-02-2016 (00:00:13)	DeFord_COMBO_R02.09
	238:5 it was	
	238:6 something that was common knowledge that	
	238:7 we thought didn't need to be done or it	
	238:8 didn't cross our mind as something that	

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238:9 needed to be put into a document.
238:10 So I don't think it was a
238:11 matter of intentionally choosing to leave
238:12 things out.

PL Affirmatives = 00:01:22

DEF Affirmatives = 00:11:29

Total Time = 00:12:51

EXHIBIT Q

Designation Run Report

Trerotola_COMBO_R02

Trerotola, Scott 01-20-2017

PL Affirmatives 00:02:33

DEF Affirmatives 00:08:45

Total Time 00:11:18



Trerotola_COMBO_R01-Trerotola_COMBO_R02

Page/Line	Source	ID
5:24 - 6:2	Trerotola, Scott 01-20-2017 (00:00:04) 5:24 Would you please state your name for the 6:1 record, please. 6:2 A. Scott Trerotola.	Trerotola_COMBO_R01.1
7:23 - 8:10	Trerotola, Scott 01-20-2017 (00:00:22) 7:23 Q. The deposition here today, I understand 7:24 that you have been a consultant for Bard; is that 8:1 correct? 8:2 A. That is correct. 8:3 Q. Are you still a consultant with Bard? 8:4 A. Yes, I am. 8:5 Q. How long have you been a consultant for 8:6 Bard? 8:7 A. Since sometime in the 1990s. 8:8 Q. Do you currently have a consulting 8:9 agreement? 8:10 A. Yes, I do.	Trerotola_COMBO_R01.22
8:17 - 8:18	Trerotola, Scott 01-20-2017 (00:00:02) 8:17 Q. And are you paid for that? 8:18 A. I am.	Trerotola_COMBO_R01.23
8:22 - 8:24	Trerotola, Scott 01-20-2017 (00:00:04) 8:22 Q. What is the hourly rate that you charge 8:23 Bard for consulting? 8:24 A. \$500.	Trerotola_COMBO_R01.24
9:24 - 10:3	Trerotola, Scott 01-20-2017 (00:00:06) 9:24 Q. Do you consult with any other type -- 10:1 any other medical device company? 10:2 A. I do consult with other medical device 10:3 companies, yes.	Trerotola_COMBO_R01.2
16:4 - 16:7	Trerotola, Scott 01-20-2017 (00:00:06) 16:4 Q. Have you served as an expert for Bard? 16:5 A. An expert witness? 16:6 Q. Yes. 16:7 A. I don't think so.	Trerotola_COMBO_R01.2
19:7 - 19:14	Trerotola, Scott 01-20-2017 (00:00:20) 19:7 Physicians rely on the company that 19:8 sells devices among other avenues to provide 19:9 information about safety of the device, correct? 19:10 A. I would disagree with that. 19:11 Q. Why?	Trerotola_COMBO_R01.4

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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19:12 A. Physicians generally rely on the medical
19:13 literature to learn about their devices and their
19:14 products they're going to use.

20:6 - 20:9

Trerotola, Scott 01-20-2017 (00:00:08)

Trerotola_COMBO_R01.8

20:6 Q. Have you implanted Bard filters?

20:7 A. I have.

20:8 Q. Do you currently implant filters?

20:9 A. Yes.

22:24 - 23:6

Trerotola, Scott 01-20-2017 (00:00:16)

Trerotola_COMBO_R01.8

22:24 Q. Well, as a physician, do you expect that
23:1 any information you receive from a company about a
23:2 medical device will be factually accurate and truthful?

23:3 A. Actually, I don't expect that.

23:4 Q. You don't?

23:5 A. I take the brochures and throw them in
23:6 the trash.

23:14 - 23:22

Trerotola, Scott 01-20-2017 (00:00:25)

Trerotola_COMBO_R01.9

23:14 Q. Do you agree that a company should, when
23:15 it provides information, promotional information about
23:16 its product, be factually accurate in that writing?

23:17 A. That's not for me to say. For me as a

23:18 physician, my belief is that I'm going to read the

23:19 medical literature, I'm going to use my own experience
23:20 and judge for myself as to whether I am going to use a
23:21 device or not.

23:22 tells me.

31:17 - 31:24

Trerotola, Scott 01-20-2017 (00:00:24)

Trerotola_COMBO_R01.9

31:17 Q. I mean, have you ever relied on anything
31:18 a sales representative from Bard told you about a
31:19 medical device, such as a filter?

31:20 A. I could tell you that everything that I

31:21 do with a device, I find independently. I'll read the

31:22 instructions for use, which are something that's just

31:23 been specifically, you know, cleared by the FDA. Like
31:24 I said, the brochures, they go in the trash.

35:17 - 35:23

Trerotola, Scott 01-20-2017 (00:00:15)

Trerotola_COMBO_R01.11

35:17 Q. Well, you know that you are here because
35:18 you are a consultant for Bard, correct?

35:19 A. That's correct.

35:20 Q. And you have consulted with Bard on

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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35:21 filters, correct?

35:22 A. Part of my consulting for Bard is with
35:23 filters.

54:6 - 54:12

Trerotola, Scott 01-20-2017 (00:00:17)

Trerotola_COMBO_R01.0

54:6 Q. Do you understand that optional means
54:7 that the filter is permanent and can also be optionally
54:8 retrieved?54:9 A. Actually, I don't -- that's not my
54:10 understanding. I would say it the other way around. I
54:11 would say that the filter is meant to be retrieved but
54:12 can remain permanent, if desired.

77:11 - 77:16

Trerotola, Scott 01-20-2017 (00:00:18)

Trerotola_COMBO_R01.02

77:11 Q. Was a feature of the retrievable filter
77:12 the ease of removing the filter?77:13 A. I wouldn't say that somebody was saying
77:14 the ease of removal, I would say the feature -- the
77:15 attractive feature to us as practicing clinicians was
77:16 the ability to retrieve the filter.

78:8 - 78:11

Trerotola, Scott 01-20-2017 (00:00:12)

Trerotola_COMBO_R01.01

78:8 Q. And the difficult retrievals may be the
78:9 result of different types of complications experienced
78:10 by the filter while it's in the patient?

78:11 A. That's correct.

80:2 - 80:10

Trerotola, Scott 01-20-2017 (00:00:18)

Trerotola_COMBO_R01.02

80:2 Q. But when it penetrates through the vena
80:3 cava wall, that does lead to a difficult retrieval,
80:4 using your words?80:5 A. I didn't say that, no. I absolutely did
80:6 not say that.80:7 Q. Is that a -- can that be a feature of a
80:8 difficult retrieval?80:9 A. Penetration of itself is not really a
80:10 feature of difficult retrieval.

83:16 - 83:18

Trerotola, Scott 01-20-2017 (00:00:07)

Trerotola_COMBO_R01.02

83:16 Q. And then when the G2 was launched, were
83:17 you using the majority of your optional filters the G2?

83:18 A. Yes.

92:1 - 92:12

Trerotola, Scott 01-20-2017 (00:00:33)

Trerotola_COMBO_R01.02

92:1 Q. Recovery fractures that you were hearing
92:2 about --

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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92:3 A. Yeah.

92:4 Q. -- understanding they were different

92:5 than your personal experience, did that, among other

92:6 things, cause a concern for patient safety?

92:7 A. That made us pay attention.

92:8 Q. And did you pay attention, among the

92:9 reasons that you paid attention, were in the interest

92:10 of patient safety, among other reasons?

92:11 A. Certainly, we would be concerned about a

92:12 fracture for safety, sure. Yes, I do say that.

93:4 - 93:7

Trerotola, Scott 01-20-2017 (00:00:12)

Trerotola_COMBO_R01.12

93:4 Q. And your understanding was that Bard was

93:5 putting the G2 out there as with improved features that

93:6 would, among other things, resist fracture?

93:7 A. That was my understanding, yes.

93:8 - 93:11

Trerotola, Scott 01-20-2017 (00:00:08)

Trerotola_COMBO_R01.13

93:8 Q. Were you aware of problems with Recovery

93:9 tilting?

93:10 A. We had personally seen problems with

93:11 Recovery tilting, yes.

93:12 - 94:2

Trerotola, Scott 01-20-2017 (00:00:47)

Trerotola_COMBO_R01.14

93:12 Q. And when Bard launched the G2, did Bard

93:13 indicate to you that the G2 had improved centering and

93:14 stability?

93:15 A. In the course of my consulting with

93:16 Bard, we had discussions about the design changes, and

93:17 one of the goals was to try to reduce tilting, yes.

93:18 Q. And that's what Bard had indicated that

93:19 they were -- was the intent behind the G2, to make an

93:20 improvement, tilt resistance over the Recovery?

93:21 A. I'm not sure that -- I can't speak to

93:22 what Bard's intention was. My understanding was that

93:23 there were two improvements. One was that the arms

93:24 were longer and the little sort of indentations on the

94:1 end to keep the legs, arms from poking in, which

94:2 supposedly would reduce fracture, would reduce tilting.

94:23 - 95:7

Trerotola, Scott 01-20-2017 (00:00:26)

Trerotola_COMBO_R01.15

94:23 Q. Did you ever talk to Bard about its

94:24 experience with tilting, whether it had -- could advise

95:1 you as to how many incidents or events they were aware

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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95:2 of at Bard that involve tilting?

95:3 A. To be honest, I don't think we would

95:4 have had that conversation, because tilting is a common

95:5 enough problem with all kinds of filters that that's

95:6 not really a conversation I would think we would have,

95:7 but I don't know for sure.

95:18 - 95:20

Trerotola, Scott 01-20-2017 (00:00:06)

Trerotola_COMBO_R01.17

95:18 Q. Is it possible that the G2 became your

95:19 exclusive optional filter?

95:20 A. Yes.

98:19 - 98:21

Trerotola, Scott 01-20-2017 (00:00:05)

Trerotola_COMBO_R01.18

98:19 Q. And for what reasons?

98:20 A. Because an alternative filter became

98:21 available.

99:4 - 99:7

Trerotola, Scott 01-20-2017 (00:00:08)

Trerotola_COMBO_R01.19

99:4 A. Yeah, I think there were some

99:5 discussions about G2 migration, but we're not talking

99:6 about big migration. I think a lot of people

99:7 misconstrue, misuse the word migration.

99:15 - 99:21

Trerotola, Scott 01-20-2017 (00:00:16)

Trerotola_COMBO_R01.20

99:15 Q. What was the issue about migration and

99:16 G2 that you had talked to other doctors about?

99:17 A. That it appeared to have a tendency to

99:18 move downward a little bit.

99:19 Q. Did you call that caudal migration?

99:20 A. That would be termed caudal migration,

99:21 yeah.

102:12 - 102:18

Trerotola, Scott 01-20-2017 (00:00:26)

Trerotola_COMBO_R01.21

102:12 Q. Is caudal migration an indication that

102:13 the filter is not remaining stable?

102:14 A. I'm going to rephrase to say that the

102:15 caudal migration is an indication that at some point

102:16 the filter moved. You said remaining unstable. That's

102:17 different. The filter moved, but then once it moves,

102:18 it may stay there.

105:18 - 105:21

Trerotola, Scott 01-20-2017 (00:00:12)

Trerotola_COMBO_R01.22

105:18 Q. And you indicated that an issue with

105:19 penetration is that it could lead to tilt?

105:20 A. Actually, penetration probably reduces

105:21 tilt, in my opinion. That's only my opinion.

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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119:15 - 119:18	Trerotola, Scott 01-20-2017 (00:00:10)	Trerotola_COMBO_R01.25
	119:15 Q. Would that be the reason you didn't	
	119:16 adopt -- I mean, it sounds to me like if you had your	
	119:17 option, you're going to stay with the G2?	
	119:18 A. We really liked the G2.	Trerotola_COMBO_R01.26
125:16 - 125:22	Trerotola, Scott 01-20-2017 (00:00:24)	
	125:16 Q. Well, if Bard had indicated to you, for	
	125:17 example, that they were making a filter, like when the	
	125:18 G2 came out, that was going to be resistant to fracture	
	125:19 and some of the problems that the Recovery had	
	125:20 experienced, you would expect Bard to test that model	
	125:21 to know that the filter could, in fact, do what they	
	125:22 said it was going to do?	Trerotola_COMBO_R01.28
125:24 - 126:5	Trerotola, Scott 01-20-2017 (00:00:10)	
	125:24 THE WITNESS: So I would expect Bard to	
	126:1 test that model, however, you said "know."	
	126:2 Nobody can know what's going to happen. You	
	126:3 can do all the testing in the world, you're	
	126:4 never going to be able to predict what's going	
	126:5 to happen in a human being.	Trerotola_COMBO_R01.29
126:7 - 126:18	Trerotola, Scott 01-20-2017 (00:00:33)	
	126:7 Q. Well, what's your understanding of the	
	126:8 purpose of testing?	
	126:9 A. The purpose of testing is to get to --	
	126:10 as close as possible to, you know, knowing, but you're	
	126:11 never going to know, but to try to simulate the	
	126:12 condition the filter is going to be in and, hopefully,	
	126:13 get it to perform in the way you want it to perform. I	
	126:14 mean, that's sort of a loosely construed sort of	
	126:15 layman's.	
	126:16 Q. So you would expect Bard to test the G2	
	126:17 filter to determine whether it was improved over the	
	126:18 Recovery?	Trerotola_COMBO_R01.30
126:20 - 126:21	Trerotola, Scott 01-20-2017 (00:00:03)	
	126:20 THE WITNESS: My understanding was that	
	126:21 such testing was done.	Trerotola_COMBO_R01.31
126:23 - 127:5	Trerotola, Scott 01-20-2017 (00:00:22)	
	126:23 Q. And that's something that you, as a	
	126:24 doctor, would expect that would be done, correct?	
	127:1 A. Speaking as a physician and as a user of	

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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127:2 - 127:5	127:2 medical devices, it would be my hope that and my 127:3 expectation that somebody presenting a device that is 127:4 expected to address a prior concern would have tested 127:5 that, yes.	
129:6 - 129:9	Trerotola, Scott 01-20-2017 (00:00:05) 129:6 Q. Were you aware that Dr. Asch had told 129:7 Bard that he had safety concerns regarding the Recovery 129:8 filter? 129:9 A. No.	Trerotola_COMBO_R01.07
129:17 - 129:19	Trerotola, Scott 01-20-2017 (00:00:11) 129:17 Q. Were you aware that Dr. Asch had told 129:18 Bard that the safety concern should be improved before 129:19 placing the filter on the market?	Trerotola_COMBO_R01.08
129:21 - 129:22	Trerotola, Scott 01-20-2017 (00:00:01) 129:21 THE WITNESS: I don't recall hearing 129:22 that.	Trerotola_COMBO_R01.09
135:12 - 135:14	Trerotola, Scott 01-20-2017 (00:00:06) 135:12 Q. And doctors have expressed to you 135:13 concerns that they had about the Recovery in terms of 135:14 the failures they were seeing?	Trerotola_COMBO_R01.07
135:16 - 135:22	Trerotola, Scott 01-20-2017 (00:00:19) 135:16 THE WITNESS: You know, this is a long 135:17 time ago, back, you know, when you're talking 135:18 about them, I mean, we talk about problems with 135:19 filters all the time, including now. Can I 135:20 tell you exactly whether a doctor came to me 135:21 and said I'm concerned about this, it might 135:22 have happened. I don't know.	Trerotola_COMBO_R01.09
177:11 - 177:13	Trerotola, Scott 01-20-2017 (00:00:05) 177:11 Q. Meaning that if they're used as a 177:12 permanent filter, they should last the life of the 177:13 patient?	Trerotola_COMBO_R01.09
177:18 - 177:23	Trerotola, Scott 01-20-2017 (00:00:12) 177:18 regulatory pathway went. That's not to say that they 177:19 were ever intended to be permanent filters. Our intent 177:20 as doctors using these was not to use them as permanent 177:21 filters. And if you look at everything I've ever 177:22 written on this subject, that's completely consistent 177:23 with what I'm saying.	Trerotola_COMBO_R01.09
178:20 - 179:3	Trerotola, Scott 01-20-2017 (00:00:20)	Trerotola_COMBO_R01.09

Trerotola_COMBO_R01-Trerotola_COMBO_R02

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178:20 Q. Were you aware that the Simon Nitinol
178:21 filter, according to Bard, virtually had no complaints
178:22 associated with it?

178:23 A. That I would strongly disagree with that
178:24 statement. We really thought the Nitinol – we
179:1 actually called it the Frightenol. We thought it was
179:2 not a good filter and didn't use it. These are the
179:3 doctors in the community.

179:4 - 179:7

Trerotola, Scott 01-20-2017 (00:00:07)

Trerotola_COMBO_R01.08

179:4 Q. Did you ever ask Bard the number of
179:5 complaints they had with the Simon Nitinol?
179:6 A. I had no reason to. I didn't use the
179:7 filter.

195:11 - 196:2

Trerotola, Scott 01-20-2017 (00:00:40)

Trerotola_COMBO_R01.21

195:11 Q. Has a patient who has experienced
195:12 complications from a Bard filter and now the question
195:13 is whether the retrieval is difficult or already has
195:14 been difficult, correct?

195:15 A. Yeah.

195:16 Q. And based upon the complication and the
195:17 difficulty, Bard will have that doctor – will contact
195:18 you and put you in touch with that doctor?

195:19 A. That's correct.

195:20 Q. And Bard will pay you to talk to that
195:21 doctor on how to address the complications that
195:22 resulted from the filter?

195:23 A. We usually have a short conversation, so
195:24 we're talking about a pretty small payment that is
196:1 really about doc to doc conversation about getting that
196:2 patient better.

5:24 - 6:2

Trerotola, Scott 01-20-2017 (00:00:04)

Trerotola_COMBO_R01.09

5:24 Would you please state your name for the
6:1 record, please.
6:2 A. Scott Trerotola.

PL Affirmatives = 00:02:33

DEF Affirmatives = 00:08:45

Total Time = 00:11:18

EXHIBIT R

Designation Run Report

Stavropoulous_Combo_R02

Stavropoulos, Spyros 02-01-2017

PL Affirmatives 00:02:11

DEF Affirmatives 00:10:13

Total Time 00:12:24



Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

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11:7 - 11:8	Stavropoulos, Spyros 02-01-2017 (00:00:02) 11:7 Q. Good morning, Doctor, 11:8 A. Good morning.	Stavropoulos_COMBO_R02.1
12:17 - 12:23	Stavropoulos, Spyros 02-01-2017 (00:00:13) 12:17 Q. Tell the jury, 12:18 if you would, your name and your current 12:19 specialty and affiliation. 12:20 A. My name is Spyros William 12:21 Stavropoulos. I am an interventional 12:22 radiologist at the University of 12:23 Pennsylvania.	Stavropoulos_COMBO_R02.2
49:16 - 49:20	Stavropoulos, Spyros 02-01-2017 (00:00:13) 49:16 Q. Did Bard ever tell you that 49:17 it was learning of migration fatalities 49:18 in the Recovery device as early as 49:19 February of 2004? 49:20 A. No.	Stavropoulos_COMBO_R02.3
57:8 - 57:12	Stavropoulos, Spyros 02-01-2017 (00:00:12) 57:8 Q. And to your knowledge, in 57:9 that entire time with the Recovery 57:10 device, Bard never told you anything 57:11 about adverse events resulting in 57:12 fatalities. Correct?	Stavropoulos_COMBO_R02.4
57:15 - 57:16	Stavropoulos, Spyros 02-01-2017 (00:00:01) 57:15 THE WITNESS: Not that I 57:16 remember.	Stavropoulos_COMBO_R02.5
62:9 - 62:11	Stavropoulos, Spyros 02-01-2017 (00:00:04) 62:9 Q. So do you consent your 62:10 patients on using the Bard devices? 62:11 A. Yes.	Stavropoulos_COMBO_R02.6
63:7 - 63:24	Stavropoulos, Spyros 02-01-2017 (00:00:33) 63:7 Q. And when you do that, do you 63:8 differentiate from one device to the 63:9 next? 63:10 A. No. 63:11 Q. Or are your relative risks 63:12 the same when you're talking about IVC 63:13 filters? 63:14 A. That is what I say for all 63:15 the different IVC filters.	Stavropoulos_COMBO_R02.10

Stavropoulos_COMBO_R02-Stavropoulous_Combo_R02

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63:16 Q. And that's your
63:17 understanding, that is, the risks are
63:18 generally the same as they relate from
63:19 one product to the next?

63:20 A. Yes.

63:21 Q. And if a company knew that
63:22 its device actually posed an increased
63:23 risk of -- I'll name a couple of what --
63:24 tilting, migration, fracturing

64:4 - 64:5 **Stavropoulos, Spyros 02-01-2017 (00:00:03)**

Stavropoulos_COMBO_R02.11

64:4 that is something
64:5 you would expect a company to tell you.
64:6 Correct?

64:9 - 64:14 **Stavropoulos, Spyros 02-01-2017 (00:00:13)**

Stavropoulos_COMBO_R02.12

64:9 THE WITNESS: As I said
64:10 before, I wouldn't expect that to come
64:11 from the company. We rely on the FDA
64:12 for safety of products. And -- and
64:13 that is more the avenue of where I
64:14 would expect that to come from.

149:8 - 149:22 **Stavropoulos, Spyros 02-01-2017 (00:00:56)**

Stavropoulos_COMBO_R02.13

149:8 Q. What period of time were you
149:9 using -- did you end up using the G2?
149:10 A. Used the G2 during the time
149:11 it was available, and then when --
149:12 because we had great results with it, we
149:13 continued to use it. And when the, you
149:14 know, G2X came out and Eclipse came out,
149:15 we started using those devices.
149:16 Q. Was the G2 a safer product
149:17 than the Recovery product in your
149:18 experience?
149:19 A. Both performed very well in
149:20 our experience, and for our patients, it
149:21 was not a dramatic difference between the
149:22 two products.

180:22 - 181:16 **Stavropoulos, Spyros 02-01-2017 (00:00:55)**

Stavropoulos_COMBO_R02.14

180:22 You participated in a study
180:23 that was published in 2011 called the
180:24 Removal of Retrievable Inferior Vena Cava

Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

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181:1 Filters with Computed Tomography Findings

181:2 indicating Tenting or Penetration of the

181:3 Inferior Vena Cava Wall. Correct?

181:4 A. Yes.

181:5 Q. Now, I've heard -- I've seen

181:6 in e-mails and other documents that you

181:7 had been working on sort of a grading

181:8 system for penetration of filters in the

181:9 caval walls. Correct?

181:10 A. Correct.

181:11 Q. And this paper that I just

181:12 referred to employs some of that grading.

181:13 doesn't it?

181:14 A. Yes.

181:15 Q. All right. And let me show

181:16 it to you. This is Exhibit 827.

182:6 - 182:7

Stavropoulos, Spyros 02-01-2017 (00:00:02)

182:6 Q. This is your paper.

182:7 Correct?

182:8 - 182:8

Stavropoulos, Spyros 02-01-2017 (00:00:01)

182:8 A. Yes.

182:9 - 182:14

Stavropoulos, Spyros 02-01-2017 (00:00:22)

182:9 Q. Now, ultimately, the

182:10 conclusion of the paper was that filters

182:11 can tent and penetrate through the IVC

182:12 wall. It's a common finding. And on CT

182:13 images obtained before retrieval, that

182:14 retrieval of these filters is safe.

182:19 - 183:3

Stavropoulos, Spyros 02-01-2017 (00:00:28)

182:19 A. Correct.

182:20 Q. But in the grading system,

182:21 you actually compare devices, including

182:22 Bard devices, to other devices.

182:23 Describe, if you would, what a Grade 0,

182:24 Grade 1, Grade 2, Grade 3 is.

183:1 A. So a Grade 0 would be no

183:2 penetration of the struts of the IVC

183:3 filter outside the wall of the IVC.

183:15 - 184:8

Stavropoulos, Spyros 02-01-2017 (00:01:08)

183:15 Q. So in that Grade 3 when a

183:16 penetration would interact with an organ
 183:17 outside of the IVC, in your study, you
 183:18 found that as compared to the Gunther
 183:19 Tulip device, the Recovery was four to
 183:20 five times more likely to have a Grade 3
 183:21 penetration. Correct? And I'm looking
 183:22 at Table 3.

183:23 A. I would disagree with that.
 183:24 This was not meant to compare among
 184:1 filter types for this type of grading
 184:2 system. There are more Recovery and G2
 184:3 filters in our study because these were
 184:4 filters that we placed and -- at Penn at
 184:5 the time. And so because there were more
 184:6 of them, that's why there's more of those
 184:7 types of filters in the study. It's not
 184:8 meant to ascribe a rate to.

184:9 - 184:19

Stavropoulos, Spyros 02-01-2017 (00:00:32)

184:9 Q. Well, you do have a rate
 184:10 presented in Table 3. Right? It says
 184:11 that 52 percent -- 52.2 percent of the
 184:12 Recoverys had a Grade 3 penetration.
 184:13 Correct?

184:14 A. In this study, among
 184:15 patients included here, there were 12
 184:16 patients that had a Grade 3
 184:17 penetration --

184:18 Q. For Recovery?

184:19 A. -- that had a Recovery, yes.

184:20 - 185:12

Stavropoulos, Spyros 02-01-2017 (00:00:39)

184:20 Q. And there were 13 patients
 184:21 with the Recovery G2, which represented
 184:22 43.3 percent of the study patients.
 184:23 Correct?

184:24 A. Yes.

185:1 Q. And when you compare that,
 185:2 the Gunther Tulip only had one Grade 3
 185:3 penetration, and the OptEase had none.
 185:4 Is that what Table 3 says?

185:5 A. For patients in this trial

Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

Page/Line	Source	ID
	185:6 or in this -- this retrospective study,	
	185:7 yes.	
	185:8 Q. Okay,	
	185:9 A. But there's many more of the	
	185:10 Recovery and the G2s in the -- in the	
	185:11 group of patients, so that's why it	
	185:12 appears that way.	
185:13 - 185:16	Stavropoulos, Spyros 02-01-2017 (00:00:09)	Stavropoulos_COMBO_R02-02
	185:13 Q. And again, the Grade 3 would	
	185:14 be penetration to organs surrounding the	
	185:15 IVC. Right?	
	185:16 A. Yes.	
194:3 - 194:4	Stavropoulos, Spyros 02-01-2017 (00:00:03)	Stavropoulos_COMBO_R02-02
	194:3 Q. Dr. Stavropoulos, my name is	
	194:4 Taylor Daly. I represent Bard.	
195:3 - 195:21	Stavropoulos, Spyros 02-01-2017 (00:00:45)	Stavropoulos_COMBO_R02-02
	195:3 Q. Of the filters you	
	195:4 undertake to retrieve, what is the	
	195:5 percentage of those filters that you're	
	195:6 finding you're capable of retrieving?	
	195:7 A. Over the last, say, five	
	195:8 years, it would be approaching 100%.	
	195:9 Q. And is that true of filters	
	195:10 that exhibit perforations, for example?	
	195:11 Or have you found you're able to retrieve	
	195:12 those?	
	195:13 A. Yes.	
	195:14 Q. Filters with certain tilts?	
	195:15 A. Yes.	
	195:16 Q. Filters that have moved,	
	195:17 perhaps, to other than the initial	
	195:18 placement spot?	
	195:19 A. Yes.	
	195:20 Q. And filters with fracture?	
	195:21 A. Yes.	
198:11 - 198:20	Stavropoulos, Spyros 02-01-2017 (00:00:29)	Stavropoulos_COMBO_R02-02
	198:11 Q. And do you make an	
	198:12 individual risk/benefit analysis for each	
	198:13 patient about when and whether to	
	198:14 retrieve the filter?	

Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

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198:15 A. Yes.

198:16 Q. Overall, how would you

198:17 describe your experience using Bard

198:18 filters, the ones you've described that

198:19 you have used from the Recovery to the

198:20 Denali?

198:23 - 199:2

Stavropoulos, Spyros 02-01-2017 (00:00:07)

Stavropoulos_COMBO_R02-01

198:23 THE WITNESS: Overall in my

198:24 experience, the Bard filters in

199:1 patients that we've placed them in

199:2 have performed well.

208:23 - 209:15

Stavropoulos, Spyros 02-01-2017 (00:00:55)

Stavropoulos_COMBO_R02-01

208:23 Q. Over your career using IVC

208:24 filters, have you known certain doctors

209:1 to like one filter and prefer to use that

209:2 over another filter?

209:3 A. Yes.

209:4 Q. Do you -- have you over --

209:5 at times preferred one filter over

209:6 another?

209:7 A. Yes.

209:8 Q. And what filters have you

209:9 preferred overall?

209:10 A. Well, one thing that comes

209:11 to mind is when optional filters came

209:12 onto the market, I preferred optional

209:13 filters to permanent filters for people

209:14 who had a time-limited need for -- for

209:15 filtration.

214:20 - 215:21

Stavropoulos, Spyros 02-01-2017 (00:00:53)

Stavropoulos_COMBO_R02-01

214:20 Q. You were asked about the

214:21 study that you did with Dr. Oh, the

214:22 removal of IVC filters with computed

214:23 tomography.

214:24 A. Yes.

215:1 Q. And you remarked that the

215:2 study had many more -- had many Bard

215:3 filters in the study. Correct?

215:4 A. Yes.

215:5 Q. And, in fact, there was

Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

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215:6 quite a small number of any other
215:7 manufacturer's filters in that study.
215:8 True?

215:9 A. Yes.

215:10 Q. And the study's protocols
215:11 were not set up to do a comparison of any
215:12 particular filter to determine -- to
215:13 ascribe a rate of perforation filter type
215:14 by filter type, was it?

215:15 A. That is true.

215:16 Q. And as a result of that
215:17 study, did you find overall good
215:18 retrievability of the Bard filters in the
215:19 study, irrespective of the degree of
215:20 perforation?

215:21 A. Yes.

220:6 - 220:9

Stavropoulos, Spyros 02-01-2017 (00:00:10)

220:6 Q. That is a percentage of
220:7 what?

220:8 A. Of the filters in patients
220:9 that were included in this analysis.

222:3 - 222:12

Stavropoulos, Spyros 02-01-2017 (00:00:28)

222:3 So if you're just looking at
222:4 the G2 population within your study, of
222:5 all of those G2s implanted, 43.3 percent
222:6 were Grade 3, that is, the strut was
222:7 going through and interfacing or
222:8 interacting with an external organ.
222:9 Correct?

222:10 A. 43.3 percent of the G2
222:11 filters in this analysis had one strut
222:12 that was interacting with...

222:13 - 222:18

Stavropoulos, Spyros 02-01-2017 (00:00:20)

222:13 Q. And of all the Gunther Tulip
222:14 devices that you studied and looked at,
222:15 that number was 12 percent that had a
222:16 Grade 3 penetration. Correct?

222:17 A. 12.5 percent, but it was of
222:18 a much smaller number, so it's not-

222:21 - 222:24

Stavropoulos, Spyros 02-01-2017 (00:00:07)

Stavropoulos_COMBO_R02-Stavropoulos_Combo_R02

Page/Line	Source	ID
223:21 - 223:24	<p>222:21 THE WITNESS: — really fair</p> <p>222:22 to compare those two percentages.</p> <p>222:23 It's not statistically valid to</p> <p>222:24 compare those two.</p> <p>Stavropoulos, Spyros 02-01-2017 (00:00:12)</p> <p>223:21 Q. And of the G2s, of the 30</p> <p>223:22 G2s implanted, 43.3 percent of them had</p> <p>223:23 Grade 3 penetrations. Correct?</p> <p>223:24 A. Correct.</p>	Stavropoulos_COMBO_R02.01
224:1 - 224:5	<p>Stavropoulos, Spyros 02-01-2017 (00:00:15)</p> <p>224:1 Q. So when you say that you</p> <p>224:2 can't compare the two, you can't compare</p> <p>224:3 a study of 8 versus a study of 30?</p> <p>224:4 A. In this study, you can't</p> <p>224:5 compare the two because of the disparity.</p>	Stavropoulos_COMBO_R02.01
224:6 - 224:7	<p>Stavropoulos, Spyros 02-01-2017 (00:00:02)</p> <p>224:6 Q. How many Recoverys were</p> <p>224:7 studied?</p>	Stavropoulos_COMBO_R02.01
224:13 - 224:18	<p>Stavropoulos, Spyros 02-01-2017 (00:00:15)</p> <p>224:13 THE WITNESS: 23.</p> <p>224:14 BY MR. MIGLIORI:</p> <p>224:15 Q. And of the 23 Recoverys,</p> <p>224:16 more than half of them were Grade 3</p> <p>224:17 penetrations. Correct?</p> <p>224:18 A. That is correct.</p>	Stavropoulos_COMBO_R02.01
224:19 - 225:1	<p>Stavropoulos, Spyros 02-01-2017 (00:00:18)</p> <p>224:19 Q. And it's still your position</p> <p>224:20 that you can't compare a study of 23 to a</p> <p>224:21 study of 8 in the Gunther Tulip.</p> <p>224:22 Correct?</p> <p>224:23 A. It's my position that this</p> <p>224:24 study was not designed to compare</p> <p>225:1 penetration rates among filters.</p>	Stavropoulos_COMBO_R02.01
<p>PL Affirmatives = 00:02:11</p> <p>DEF Affirmatives = 00:10:13</p> <p>Total Time = 00:12:24</p>		
PL Affirmatives	DEF Affirmatives	Page 9/9

EXHIBIT S

Designation Run Report

Syed 03-02-18 Booker Depo Trial Run V6

Syed, Mehdi 03-02-2018

Our Designations 00:15:32

Their Designations 00:03:30

Our Counter Counters 00:00:09

Total Time 00:19:11



03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
38:17 - 39:3	Syed, Mehdi 03-02-2018 (00:00:37) 38:17 Q. I'm going to focus first, 38:18 if that's all right, on the 10-K for December 31, 38:19 2016, which is Exhibit 1131, if that's all right. 38:20 A. Yup. 38:21 Q. So this document is a document in 38:22 which the company reports publicly it's financial 38:23 condition, correct? 38:24 A. That is correct. 38:25 Q. And it is certified by its CEO, in 39:1 this case Tim Ring, as being accurate, truthful 39:2 and complete, correct? 39:3 A. That is correct.	03_29_18 V6.1
40:16 - 40:20	Syed, Mehdi 03-02-2018 (00:00:15) 40:16 Q. And like the 10-K, this 10-Q is 40:17 also signed by the president or CEO of Bard and 40:18 certified as being accurate, truthful and 40:19 complete; is that correct? 40:20 A. That is correct.	03_29_18 V6.2
41:6 - 41:23	Syed, Mehdi 03-02-2018 (00:00:42) 41:6 And the 10-Q is a quarterly 41:7 submission, correct? 41:8 A. That is correct. 41:9 Q. And the 10-Q we have here, 41:10 Exhibit 1132, is for the end of the third quarter 41:11 of 2017, correct? 41:12 A. That is correct. 41:13 Q. So it contains, if we look at the 41:14 financial information and its disclosures, 41:15 information specific to the three months that 41:16 were ended September 30, and it also has 41:17 cumulative information for the nine months in 41:18 2017 January through September, correct? 41:19 A. That is correct. 41:20 Q. And this, Exhibit 1132, is the most 41:21 recent financial filing by C.R. Bard; is that 41:22 correct? 41:23 A. That is correct.	03_29_18 V6.3
43:7 - 43:8	Syed, Mehdi 03-02-2018 (00:00:11) 43:7 Let me ask if you would	03_29_18 V6.4

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
44:5 - 44:23	<p>43:8 turn on Exhibit 1131 to what is Page II-2.</p> <p>Syed, Mehdi 03-02-2018 (00:00:34)</p> <p>44:5 Q. one of the first items under</p> <p>44:6 "Income Statement Data" is "Net sales." Do you</p> <p>44:7 see that?</p> <p>44:8 A. I do.</p> <p>44:9 Q. And immediately under that is "Net</p> <p>44:10 income." Do you see that?</p> <p>44:11 A. I do.</p> <p>44:12 Q. And net income is, in layman terms,</p> <p>44:13 profit?</p> <p>44:14 A. That is correct.</p> <p>44:15 Q. So if we wanted to see C.R. Bard's</p> <p>44:16 profit for the year, we would look at that number</p> <p>44:17 which is \$531,400. Do you see that?</p> <p>44:18 A. It is in thousands of dollars</p> <p>44:19 but --</p> <p>44:20 Q. Well, you've anticipated my next</p> <p>44:21 question. That's actually 531,400,000; is that</p> <p>44:22 correct?</p> <p>44:23 A. That is correct.</p>	03_29_18 V6.5
45:3 - 45:18	<p>Syed, Mehdi 03-02-2018 (00:00:39)</p> <p>45:3 Q. So for any of these numbers other</p> <p>45:4 than share amounts, we should add -- or, sorry,</p> <p>45:5 per share amounts we should add three zeros at</p> <p>45:6 the end?</p> <p>45:7 A. That is correct.</p> <p>45:8 Q. So in 2016, Bard -- C.R. Bard's</p> <p>45:9 profit was \$531,400,000; is that correct?</p> <p>45:10 A. That is correct.</p> <p>45:11 Q. And for 2015, it was \$135,000,400?</p> <p>45:12 A. That is correct.</p> <p>45:13 Q. And 2014, \$294,000,500?</p> <p>45:14 A. That is correct.</p> <p>45:15 Q. And for 2013, \$689,800,000?</p> <p>45:16 A. That is correct.</p> <p>45:17 Q. And, finally, 2012, \$530,100,000?</p> <p>45:18 A. That is correct.</p>	03_29_18 V6.6
46:9 - 46:15	<p>Syed, Mehdi 03-02-2018 (00:00:24)</p> <p>46:9 Q. Okay. And if we want to find out</p>	03_29_18 V6.7

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
46:10	the profit for the third quarter of 2017, we	
46:11	would look at the 10-Q, correct?	
46:12	A. That is correct.	
46:13	Q. And if I look at Page 3 of that	
46:14	document, there are financial statements that	
46:15	start on that page. You actually have to flip a	
46:21 - 47:3	Syed, Mehdi 03-02-2018 (00:00:19)	03_29_18 V6.8
46:21	Q. And you'll see there for the nine	
46:22	months ended September 30, 2017, the net income	
46:23	or profit was \$411,900,000, correct?	
46:24	A. Yes, the net income was 411	
46:25	thousand nine hundred thousand dollars.	
47:1	Q. You just said -- let me ask again,	
47:2	\$411,900,000, correct?	
47:3	A. That's right.	
47:12 - 47:14	Syed, Mehdi 03-02-2018 (00:00:09)	03_29_18 V6.9
47:12	Q. from 2012	
47:13	through third quarter 2017, the total profit was	
47:14	\$2,593,100,000, correct?	
47:17 - 47:18	Syed, Mehdi 03-02-2018 (00:00:04)	03_29_18 V6.10
47:17	A. That is the sum of all of those net	
47:18	income numbers for those periods, that's correct.	
58:1 - 58:7	Syed, Mehdi 03-02-2018 (00:00:12)	03_29_18 V6.11
58:1	Would you agree with me that net	
58:2	worth is determined by the amount by which a	
58:3	company's assets exceed its liabilities?	
58:4	A. That is correct.	
58:5	Q. And sometimes in accounting	
58:6	parlance that's called owner's equity.	
58:7	A. That is correct.	
58:17 - 59:5	Syed, Mehdi 03-02-2018 (00:00:28)	03_29_18 V6.12
58:17	Q. So shareholders' investment or	
58:18	owners' equity is the net worth of the company as	
58:19	demonstrated on these financial statements,	
58:20	correct?	
58:21	A. That is correct.	
58:22	Q. And as of December 31, 2016, the	
58:23	number that Bard determined for its -- with its	
58:24	accountants for its net worth was \$1,675,100,000,	
58:25	correct?	

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
	59:1 A. That is the number for the	
	59:2 shareholders' investment, that's correct.	
	59:3 Q. Which again is the net worth,	
	59:4 correct?	
	59:5 A. That's correct	
59:6 - 59:7	Syed, Mehdi 03-02-2018 (00:00:11)	03_29_18 V6.13
	59:6 Q. If we look at the 10-Q, three	
	59:7 months later, at the end of September 2017	
59:9 - 59:14	Syed, Mehdi 03-02-2018 (00:00:16)	03_29_18 V6.14
	59:9 On its balance sheet, which is at Page 5,	
	59:10 it has a total shareholders' investment of -- are	
	59:11 you there?	
	59:12 A. I am.	
	59:13 Q. 2,017,900,000, correct?	
	59:14 A. That is correct.	
60:1 - 60:7	Syed, Mehdi 03-02-2018 (00:00:32)	03_29_18 V6.15
	60:1 Q. So 1,675,100,000 as of December 31,	
	60:2 2016, and \$2,017,900,000 as of September 30,	
	60:3 2017, correct?	
	60:4 A. That is correct.	
	60:5 Q. Would you agree that the net worth	
	60:6 of a company is affected by the amount of	
	60:7 dividends a company issues to its shareholders?	
60:9 - 60:25	Syed, Mehdi 03-02-2018 (00:00:53)	03_29_18 V6.16
	60:9 A. It does have an impact on it.	
	60:10 Q. And, in fact, to the extent that a	
	60:11 company pays out dividends to its shareholders,	
	60:12 that reduces the company's assets, and therefore	
	60:13 it reduces directly the net worth of the company,	
	60:14 correct?	
	60:15 A. That is correct.	
	60:16 Q. And as a publicly-traded company,	
	60:17 C.R. Bard over time paid out dividends to its	
	60:18 shareholders, correct?	
	60:19 A. That is correct.	
	60:20 Q. And, in fact, if we look at the	
	60:21 10-K, you can find that the dividends are	
	60:22 identified at least -- well, the full amount are	
	60:23 identified on Page II-1, which is immediately	
	60:24 before the "Selected Financial Data" we looked at	

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
61:2 - 61:9	60:25 previously. Do you see that? Syed, Mehdi 03-02-2018 (00:00:25)	03_29_18 V6.17
	61:2 A. I do see that.	
	61:3 Q. And it says the company paid cash	
	61:4 dividends of 74.6 million or \$1 per share in 2016	
	61:5 and 69.4 million or 92 cents per share in 2015,	
	61:6 correct?	
	61:7 A. That is correct.	
	61:8 Q. And we also see, if we look at the	
	61:9 "Selected Financial Data" chart on the next page,	
61:16 - 62:9	Syed, Mehdi 03-02-2018 (00:00:42)	03_29_18 V6.18
	61:16 Q. We can see cash dividends	
	61:17 paid per share for each year, correct?	
	61:18 A. Yes.	
	61:19 Q. And so for 2014, there was 86 cents	
	61:20 per share paid in cash dividends out to the	
	61:21 shareholders of C.R. Bard, correct?	
	61:22 A. That is correct.	
	61:23 Q. And it also tells us two rows down	
	61:24 from that the weighted average common shares	
	61:25 outstanding, correct?	
	62:1 A. That is correct.	
	62:2 Q. So we can actually calculate,	
	62:3 roughly, the dividend payment that was made in	
	62:4 2014 from those two numbers, correct?	
	62:5 A. Roughly, if you do the math, yes.	
	62:6 Q. Sure. And I gave you a calculator	
	62:7 earlier. Do you mind? Would you multiply	
	62:8 75,600,000 shares by 86 cents and tell us what	
	62:9 you get?	
62:11 - 62:11	Syed, Mehdi 03-02-2018 (00:00:10)	03_29_18 V6.19
	62:11 A. 65,016,000.	
62:15 - 62:17	Syed, Mehdi 03-02-2018 (00:00:06)	03_29_18 V6.20
	62:15 So that's	
	62:16 roughly 65 million in 2014, correct?	
	62:17 A. That is correct.	
63:1 - 63:12	Syed, Mehdi 03-02-2018 (00:00:43)	03_29_18 V6.21
	63:1 Q. Let's look at 2013. 82	
	63:2 cents a share and a weighted average common	
	63:3 outstanding -- shares outstanding, 79,300,000.	

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

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63:4 A. I get 65,026,000.

63:5 Q. That's what I got as well. So,

63:6 again, roughly, 65 million or approximately 65

63:7 million, if we round it, for 2013, correct?

63:8 A. Correct.

63:9 Q. Let's do the same thing, if you

63:10 don't mind, for 2012. 78 cents cash dividend per

63:11 share and 83,300,000 weighted average common

63:12 shares outstanding.

63:14 - 63:17

Syed, Mehdi 03-02-2018 (00:00:10)

03_29_18 V6.22

63:14 A. I get 64,974,000.

63:15 Q. I got that as well. So, again,

63:16 roughly, 65 -- rounded to 65 million, correct?

63:17 A. That is correct.

64:3 - 64:4

Syed, Mehdi 03-02-2018 (00:00:05)

03_29_18 V6.23

64:3 Bard issued dividends in 2017, correct?

64:4 A. That is correct.

65:1 - 65:13

Syed, Mehdi 03-02-2018 (00:00:26)

03_29_18 V6.24

65:1 Q. This indicates that there were --

65:2 in 2016, there's an NA, which I think doesn't

65:3 mean anything, must be an entry error, but it

65:4 indicates in 2017 there were four dividends of 26

65:5 cents each. Do you see that?

65:6 A. I do see that.

65:7 Q. Would you expect that to be about

65:8 right based on your experience?

65:9 A. I would expect it to be correct,

65:10 yes.

65:11 Q. Which totals I believe a dollar

65:12 four in dividends that year, correct?

65:13 A. That is correct.

69:2 - 69:7

Syed, Mehdi 03-02-2018 (00:00:19)

03_29_18 V6.25

69:2 if we use that 72,892,372 shares as our best

69:3 guess of number of outstanding shares in 2016,

69:4 understanding that it varies overtime, we can

69:5 roughly calculate the dividend paid in 2017 by

69:6 Bard, correct?

69:7 A. Yes, you can calculate that.

69:11 - 69:11

Syed, Mehdi 03-02-2018 (00:00:01)

03_29_18 V6.26

69:11 Q. Would you do that for me

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

Page/Line	Source	ID
69:15 - 69:17	Syed, Mehdi 03-02-2018 (00:00:17) 69:15 Q. So 72,892,372 times a dollar four 69:16 in dividends. 69:17 A. I get 75,808,000.	03_29_18 V6.27
70:16 - 70:18	Syed, Mehdi 03-02-2018 (00:00:07) 70:16 Q. So on that assumption, I've created 70:17 1138, which is a summary of the calculations we 70:18 just did	03_29_18 V6.28
71:10 - 71:13	Syed, Mehdi 03-02-2018 (00:00:09) 71:10 Q. So would you use the 71:11 handy dandy calculator and check my math and make 71:12 sure I didn't mess up again and see if that total 71:13 for those years is as set forth in this chart?	03_29_18 V6.29
71:16 - 71:20	Syed, Mehdi 03-02-2018 (00:00:16) 71:16 A. The total is correct. 71:17 Q. Thank you. So it's \$414,800,000 71:18 from 2012 to 2017 that was paid out as -- 71:19 approximately was paid out as shareholder 71:20 dividends by C.R. Bard, correct?	03_29_18 V6.30
71:23 - 71:23	Syed, Mehdi 03-02-2018 (00:00:01) 71:23 A. That is correct.	03_29_18 V6.31
72:7 - 72:8	Syed, Mehdi 03-02-2018 (00:00:05) 72:7 Q. I'd ask you to pull from in front 72:8 of you what's been marked as Exhibit 1133.	03_29_18 V6.32
72:16 - 72:25	Syed, Mehdi 03-02-2018 (00:00:26) 72:16 Q. And this document is called a 72:17 "Schedule 14A, Information Required In Proxy 72:18 Statement," correct? 72:19 A. That is what it says, that's 72:20 correct. 72:21 Q. And what is the purpose of this 72:22 document? 72:23 A. It outlines executive compensation, 72:24 details of executive share-base compensation, 72:25 directors compensation and so on.	03_29_18 V6.33
73:1 - 73:2	Syed, Mehdi 03-02-2018 (00:00:03) 73:1 Q. And if we turn to page 51 of this 73:2 document	03_29_18 V6.34
73:10 - 73:16	Syed, Mehdi 03-02-2018 (00:00:18) 73:10 That is a summary compensation table,	03_29_18 V6.35

03_29_18 V6-Syed 03-02-18 Booker Depo Trial Run V6

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73:11 correct?

73:12 A. That is what it says, yes.

73:13 Q. And this is where the company

73:14 identifies its highest paid officers?

73:15 A. I believe it's the CEO, COO, CFO

73:16 and then the next two highest paid officers.

74:5 - 74:7

Syed, Mehdi 03-02-2018 (00:00:11)

03_29_18 V6.36

74:5 Q. I'd like to focus just on the first

74:6 three, the CEO, the COO and the CFO of the

74:7 company, Mr. Ring, Mr. Weiland and Mr. Holland.

74:15 - 75:8

Syed, Mehdi 03-02-2018 (00:00:43)

03_29_18 V6.37

74:15 Q. The last column, it

74:16 has a number of columns where it breaks out the

74:17 various components of their compensation,

74:18 correct?

74:19 A. That is correct.

74:20 Q. And the -- among the things that

74:21 they receive are a salary, stock awards, option

74:22 awards, non-equity incentive plan compensation, a

74:23 column for change in pension value and

74:24 non-qualified deferred compensation earnings, and

74:25 then a final one that says all other

75:1 compensation, correct?

75:2 A. That is correct.

75:3 Q. And the idea of this is to give you

75:4 the full value -- the full disclosure of all of

75:5 their compensation and the value of that

75:6 compensation each year, correct?

75:7 ***

75:8 A. That is correct.

76:22 - 76:25

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76:22 So that tells us

76:23 that for 2016 Mr. Ring's total compensation was

76:24 \$12,626,500; is that correct?

76:25 A. That is correct.

77:2 - 77:7

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77:2 Q. And in 2015, his total compensation

77:3 was \$11,744,838 thousand, correct?

77:4 A. Correct.

77:5 Q. And in 2014, his total compensation

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Page/Line	Source	ID
77:12 - 78:3	<p>77:6 was \$10,840,935; is that correct?</p> <p>77:7 A. That is correct.</p> <p>Syed, Mehdi 03-02-2018 (00:00:37)</p> <p>77:12 Q. If we look</p> <p>77:13 at Mr. Weiland, his total compensation in 2016</p> <p>77:14 was \$7,121,005, correct?</p> <p>77:15 A. Yes.</p> <p>77:16 Q. And his total compensation in 2015</p> <p>77:17 was \$6,920,674, correct?</p> <p>77:18 A. Correct.</p> <p>77:19 Q. And in 2014, it was \$7,029,873,</p> <p>77:20 correct?</p> <p>77:21 A. Correct.</p> <p>77:22 Q. And I won't go through</p> <p>77:23 Mr. Holland's, but his -- his appear to be for</p> <p>77:24 2016 through '14 backwards, 3.9, 3.6 and 2.6</p> <p>77:25 million; is that correct?</p> <p>78:1 ***</p> <p>78:2 ***</p> <p>78:3 A. That is correct.</p>	03_29_18 V6.40
78:18 - 78:20	<p>Syed, Mehdi 03-02-2018 (00:00:12)</p> <p>78:18 Q. Would you agree with me that one</p> <p>78:19 way to measure the value of something is how much</p> <p>78:20 it costs to acquire it?</p>	03_29_18 V6.41
78:22 - 78:25	<p>Syed, Mehdi 03-02-2018 (00:00:10)</p> <p>78:22 A. That is one way to look at it. It</p> <p>78:23 depends on what you're measuring. It depends</p> <p>78:24 on -- it could be different by the type of</p> <p>78:25 resource.</p>	03_29_18 V6.42
79:12 - 79:16	<p>Syed, Mehdi 03-02-2018 (00:00:10)</p> <p>79:12 Q. And so if I -- if I buy a</p> <p>79:13 candy bar at the store outside where we are right</p> <p>79:14 now for a dollar, we could probably agree that</p> <p>79:15 it's worth a dollar, correct?</p> <p>79:16 A. That is correct.</p>	03_29_18 V6.43
80:12 - 80:22	<p>Syed, Mehdi 03-02-2018 (00:00:38)</p> <p>80:12 Q. The very bottom of the first page</p> <p>80:13 of the 10-K. It says, "The aggregate market</p> <p>80:14 value of the voting stock held by nonaffiliates</p> <p>80:15 of the registrant was approximately 17 million --</p>	03_29_18 V6.44

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Page/Line	Source	ID
	80:16 excuse me, \$17,273,587,263 based on the closing 80:17 price of stock traded on the New York Stock 80:18 Exchange on June 30, 2016." 80:19 A. That is -- that is right. 80:20 Q. So that would be a measurement of 80:21 that value as of the date June 30, 2016? 80:22 A. That's correct.	
92:9 - 92:15	Syed, Mehdi 03-02-2018 (00:00:20) 92:9 Among its abilities to pay a 92:10 punitive damage award would you agree a factor 92:11 would be the amount of cash or cash equivalents 92:12 that Bard or C.R. Bard had on hand? 92:13 A. That is correct. If Bard were the 92:14 standalone entity, that would be one way to 92:15 measure that ability.	03_29_18 V6.45
93:1 - 93:4	Syed, Mehdi 03-02-2018 (00:00:12) 93:1 Q. And as of December 31, 2016, the 93:2 cash and cash equivalents of C.R. Bard was \$905 93:3 million, correct? 93:4 A. That is correct.	03_29_18 V6.46
93:13 - 93:15	Syed, Mehdi 03-02-2018 (00:00:10) 93:13 Q. As of September 30, 2017, the cash 93:14 and cash equivalents is \$1,158,100,000, correct? 93:15 A. That is correct.	03_29_18 V6.47
104:12 - 105:5	Syed, Mehdi 03-02-2018 (00:00:29) 104:12 Q. Good afternoon, Mr. Syed. I've got 104:13 a couple questions just so the Jury understands a 104:14 bit more about your background. 104:15 A. Sure. 104:16 Q. Tell us please where you live? 104:17 A. I live in East Greenwich, Rhode 104:18 Island. 104:19 Q. Do you have children? 104:20 A. I do. 104:21 Q. How many? 104:22 A. Three. 104:23 Q. What are their ages? 104:24 A. 12, 9 and almost 7. 104:25 Q. How long have you worked for Bard? 105:1 A. A little over 23 years.	03_29_18 V6.48

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105:2 Q. And it's always been in a capacity
105:3 of reviewing the finances for the company?

105:4 A. I have been in the finance function
105:5 all along, yeah.

106:1 - 107:2

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106:1 Now, as an initial matter,
106:2 Mr. Syed, you understand that the lawsuit in
106:3 which you are testifying about has to do with
106:4 Bard's IVC filter products, right?
106:5 A. That is correct.
106:6 Q. Are IVC filters the only product
106:7 that Bard makes?
106:8 A. No, Bard makes several products,
106:9 that's just of them.
106:10 Q. Can you give us and the Jury,
106:11 please, an understanding of the range of
106:12 different types of products that Bard makes?
106:13 A. Also they make surgical equipment,
106:14 meshes, hemostats, biopsy equipment, stents,
106:15 scrubs and such.
106:16 Q. Now, if you take a look at 1134,
106:17 Mr. Stoller, called that "C.R. Bard Profit 2012 -
106:18 Sept. 2017." Do you see that?
106:19 A. I do see that.
106:20 Q. Now, approximately what percent of
106:21 that profit at any given year is attributable to
106:22 the sale of Bard's IVC filter products?
106:23 A. A very small fraction.
106:24 Q. Can you give us a ballpark of what
106:25 that fraction might be?
107:1 A. It would be a fraction of 1
107:2 percent.

107:5 - 108:6

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107:5 Q. the other two exhibits that we
107:6 were talking about have to do with 1138
107:7 shareholder dividends and 1136 stockholder
107:8 investment. I want to talk about those for just
107:9 a minute.
107:10 A. Okay.
107:11 Q. I believe you testified previously

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Page/Line	Source	ID
	107:12 that Bard was a publicly-owned company, right?	
	107:13 A. That is correct.	
	107:14 Q. What does it mean to be a	
	107:15 publicly-owned company?	
	107:16 A. That means that anyone in the	
	107:17 public can purchase shares of C.R. Bard. It's	
	107:18 open to purchase by the general public.	
	107:19 Q. What exactly is a shareholder?	
	107:20 A. A shareholder is somebody who owns	
	107:21 a portion of the company.	
	107:22 Q. What percentage of the shares of	
	107:23 Bard are owned by the general public as opposed	
	107:24 to, say, owned by the top executives of the	
	107:25 company?	
	108:1 A. Over 99 percent.	
	108:2 Q. So the Jury understands, Bard is	
	108:3 owned over 99 percent by regular investors just	
	108:4 like any of the people sitting in the courtroom	
	108:5 today, right?	
	108:6 A. That is correct.	
108:8 - 108:15	Syed, Mehdi 03-02-2018 (00:00:22)	03_29_18 V6.51
	108:8 Q. Can you give the Jury some type of	
	108:9 idea about who the primary shareholders are for	
	108:10 Bard?	
	108:11 A. So if I look at the investor	
	108:12 profile, our top three investors are mutual	
	108:13 funds, and they're also asset management	
	108:14 companies that manage assets of pension funds,	
	108:15 foundations, charities, endowments and such.	
112:15 - 112:16	Syed, Mehdi 03-02-2018 (00:00:03)	03_29_18 V6.52
	112:15 Q. You would agree that safety is of	
	112:16 paramount concern for Bard, right?	
112:18 - 112:21	Syed, Mehdi 03-02-2018 (00:00:05)	03_29_18 V6.53
	112:18 A. Absolutely.	
	112:19 Q. Bard wouldn't sell a product	
	112:20 regardless of whether it made a profit if that	
	112:21 product wasn't safe, right?	
112:25 - 113:4	Syed, Mehdi 03-02-2018 (00:00:12)	03_29_18 V6.54
	112:25 A. That is correct.	
	113:1 Q. Now we talked about percentage of	

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Page/Line	Source	ID
113:7 - 113:11	<p>113:2 profits, but I also wanted to ask you what 113:3 percentage of Bard's net value is attributable to 113:4 the sale of filter products? Syed, Mehdi 03-02-2018 (00:00:08) 113:7 A. Net value or net sales? 113:8 Q. Net sales. Excuse me. What 113:9 percentage of Bard's net sales is attributable to 113:10 filter products? 113:11 A. Less than 1 percent.</p>	03_29_18 V6.55
116:4 - 116:8	<p>Syed, Mehdi 03-02-2018 (00:00:06) 116:4 Q. It's one of a lot of products you 116:5 guys sell? 116:6 A. That is correct. 116:7 Q. And in every one of them you want 116:8 to make a profit, correct?</p>	03_29_18 V6.56
116:10 - 116:11	<p>Syed, Mehdi 03-02-2018 (00:00:02) 116:10 A. Logically, yes, we want to make a 116:11 profit.</p>	03_29_18 V6.57

Our Designations = 00:15:32

Their Designations = 00:03:30

Our Counter Counters = 00:00:09

Total Time = 00:19:11